SpO_2-average: Defines the period for SpO_2-Measurement. *The algorithm uses a data block from the LNOP®-sensor of a length defined here. The data block is organised as a ring memory, where the oldest data is overwritten by the actual data.*

LCD power save: Enables the message 'LCD power-save Mode' (see Fig. 4 on page 11) to be displayed.

LCD brightness: Defines the brightness of the LCD display.

only available in expert mode:

Wave display: Defines, if graphs can be displayed or not.

Buzzer frequency: Defines the frequency (tone) of the monitor buzzer.

Delete memory: Immediately deletes the alarm episode memory. **This cannot be revoked!** You should consider transferring the data to a PC before selecting this option. After completion of the command this setting is reset to 'NO'.

Pre-alarm time: Defines the duration of the pre-alarm period to be stored.

Post-alarm time: Defines the post-alarm period. See 'Pre-alarm period'.

Memory mode: Defines, if data is stored only on alarms ('Event') or permanent. The permanent storage mode might be of interest for physicians. *In permanent mode the monitor stores episodes of 2.5 minutes one after the other.*

Overwrite mode: Defines, how the monitor handles an out-of-memory-problem. It can overwrite the oldest episodes or stop writing. *At every start-up this is set to 'Overwrite'.*

Factory setting: Reactivates the factory default settings. **Caution: All individual settings will be overwritten!**

Date/time settings

Day (num.): Correction of the day in the internal clock.

Month: Correction of the month in the internal clock

Year: Correction of the year in the internal clock

Hour: Correction of the hour in the internal clock

Minute: Correction of the minute in the internal clock

Expert mode

Expert mode: Activates the expert mode after entering the correct password. When activated, the menus 'Monitor Settings' and 'System Settings' are extended to include functions primarily designed for clinicians e.g. activation of silent alarms and settings controlling the data memory.

GeTeMed mode: Only for internal purposes of GeTeMed.

Ordering information

Complete system

The complete system consists of the following items:

- 1 VitaGuard® VG300 monitor
- 1 SpO_2 patient cable PC08, 1 LNOP® SpO_2 sensor
- 1 mains power adapter NA2000-2, 1 set of batteries
- 1 pouch with straps
- 1 user manual, 1 license agreement

Accessories

Please quote the following order numbers when ordering replacements.

Item	Order number
VitaGuard® Monitor VG 300 (complete system with Masimo SET®)	**72022**
Power adapter NA2000-2	**72126**
Pouch with straps	**72186**
Masimo SpO2 patient cable PC08 (2,44m)	**70257**
Masimo SpO2 patient cable PC12 (3,66m)	**70258**
Masimo LNOP®-Neo sensor (neonates < 10kg)	**70251**
Masimo LNOP®-NeoPt sensor (pre-term neonates < 1kg)	**70250**
Masimo LNOP®-Pdt sensor (paediatric sensor 10 – 50kg)	**70252**
User manual (English)	**72312**
Alarm chart (English)	**70321**
User manual (German)	**72311**
Alarm chart (German)	**70320**
Alarm chart (Turkish)	**70322**
VitaGuard® packaging	**72902**
External alarm unit EA1000	**70003**
External alarm connector cable (10m)	**70004**
Car adapter NAK1500	**72127**

Tab. 9 Ordering information for accessories to VitaGuard® VG 300.

Ordering address

Place your order at your local dealer or contact GeTeMed:

GeTeMed GmbH
Oderstr. 59, **D-14513 Teltow, Germany**
Telephone +49 3328 3942-0
Fax +49 3328 3942-99
E-Mail info@getemed.de
Web www.getemed.de

play structure' on page 12ff, the values and factory defaults are given in 'Integrated menus' on page 23ff and in Tab. 2 to Tab. 4.

The following explanations are given in the order of their appearance in the menu.

Monitor settings

Lower HR limit: Lower limit for the pulse rate, that, if fallen below, generates an alarm.

Upper HR limit: Upper limit for the pulse rate, that, if exceeded, generates an alarm.

Tone (Pulse) Defines, if an acoustic signal is given at every recognised pulse.

Lower SpO2 limit: Lower limit for SpO_2, that, if fallen below, generates an alarm.

Upper SpO2 limit: Upper limit for SpO_2, that, if exceeded, generates an alarm.

only available in expert mode:
The so called '**Expert mode**' can be activated by entering the right password. When activated, the 'Monitor Settings' menu and the 'System Settings' menu are extended to include functions primarily designed for clinicians e.g. activation of silent alarms and settings controlling the data memory.

Silent lower HR: Ditto like lower HR limit, but this generates a silent alarm, if exceeded. *Silent alarms save, if programmed, data like a real alarm, but do not generate a user alarm –so being 'silent'. This kind of alarm can be of interest for the clinician.*

Silent upper HR: See 'upper HR limit', but generates a silent alarm.

Silent lower SpO2: See 'lower SpO2 limit', but generates a silent alarm.

Silent upper SpO2: See 'upper SpO2 limit', but generates a silent alarm.

Bradycardia delay: Delay between recognition of a bradycardia (pulse rate to low) and generation of the appropriate alarm.

Tachycardia delay: Ditto like tachycardia (pulse rate to high).

SpO2 lower delay: Ditto for falling below the lower SpO_2 limit.

SpO2 upper delay: Ditto for exceeding the upper SpO_2 limit.

System settings

Clear trends Immediately clears the trend memory. **This cannot be revoked!** After completion of the command this setting is reset to 'NO'.

SpO_2 perfusion: Defines the algorithm to estimate SpO_2. There is a normal and a special mode for patients with low Perfusion.

V. Appendix

Special function - Immediate data storage

Press both <INFO/Δ> and <GRAPHIC/∇> simultaneously. Data will automatically be stored for two minutes. The resulting episode will contain data for one minute prior to pressing the buttons and one minute thereafter. The following data will be stored:

- Date and time of the event.
- Monitor setup at time of the event (lower and upper limits.)
- SpO_2- and pulse rate (minimal, medium and maximal Value in the alarm period)
- Plethysmogram

Compliance log

The compliance memory has room for 256 events. The oldest events are automatically removed to make room for new ones. The following events are registered:

- Monitor on /off.
- SpO_2 monitoring on/ off.
- System reset from key panel.
- System reset from PC.
- Episodes removed (Number of deleted episodes).
- Error events from VitaGuard® VG 300's internal Masimo SpO_2 module (MS-3 board).

The following data is stored with each event:

- The time and date of the event.
- Monitoring settings (upper and lower limits).

The log can be examined on the monitor by pressing <INFO/Δ> once followed by pressing <GRAPHIC/∇> twice. To scroll, press <INFO/Δ>. The error codes delivered by the SpO_2 module are listed in 'Error codes' on page 45.

Explanation of the menu settings

Following you'll find an explanation of all menu settings in the monitor VitaGuard® VG 300 in the menu structures order. Explanations to the menu structure itself and on how to operate the menus can be found in 'Monitor dis-

Masimo SET technology

Principle of operation

Masimo's SET® (SET – Signal Extraction Technology®) pulse oximeter is based on three principles:

1. Oxyhaemoglobin and deoxyhaemoglobin have different red and infrared light absorption (spectrophotometry).
2. The arterial blood volume in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
3. Arterio-venous shunting is highly variable and fluctuating absorbency by venous blood is a major component of noise during the pulse.

The Masimo SET® pulse oximeter as well as traditional pulse oximetry determine SpO_2 by passing red and infrared light into a capillary bed and measure changes in light absorption during the pulsatile cycle. Red and infrared light emitting diodes (LEDs) in oximetry sensors serve as light sources, a photodiode serves as the photodetector.

Traditional pulse oximeters (TPO)

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the sensor region passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelength, 660 nm and 940 nm:

$$S(660) = AC(660)/DC(660)$$
$$S(940) = AC(940)/DC(940)$$

The oximeter then calculates the ratio of these two arterial pulse-added signals:

$$R = S(660)/S(940)$$

This value of R is used to find the saturation SpO_2 in a look-up table build into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

Masimo SET® pulse oximeter

The Masimo SET® pulse oximeter assumes that the arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of the noise during the pulse. The SpO_2 module (MS-3 board) decomposes S(660) and S(940) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

S(660) = S1 + N1
S(940) = S2 + N2
R = S1/S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation in the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies. The above equations are combined and a noise reference (N') is determined:

N' = S(660) – R * S(940)

If there is no noise N' = 0: then S(660) = R * S(940) which is the same relationship for TPO.

The equation for the noise reference N' is based on the value of R, the value being seeked to determine the SpO_2. The MS-3 software sweeps through possible values of R that correspond to SpO_2 values between 1 % and 100 % and generate an N' value for each of these R values. The S(660) and S(940) signals are processed with each possible N' noise reference through an adaptive correlation canceller (ACC) which yields an output power for each possible value of R (i.e. each possible SpO_2 from 1 % to 100 %). The result is a Discrete Saturation Transform (DST™) plot as shown in Fig. 15, where R corresponds to SpO_2 = 97%.

The DST plot has at least one peak, caused by the arterial pulse. This peak shows, that at the associated SpO_2 value the effective noise cancellation was especially effective, because a well defined source of noise, the arterial pulse variation, was identified.

The DST plot may show more peaks with even higher peak values, caused by other sources of noise (e.g. venous variations of light absorbance). But because venous

Guarantee conditions

We provide the following guarantee for VitaGuard®:

1. GeTeMed guarantees that all VitaGuard® devices with the exception of all consumables such as SpO_2-sensors, batteries and packaging material are free from faults for one year after delivery. This guarantee is provided in addition to the statutory warrantee.
2. If a fault develops in the VitaGuard® monitor within the first year after delivery, GeTeMed will repair or replace – as GeTeMed decides – the defective monitor free of charge. The customer must to prove that the fault showed up within the first year after delivery.
3. To process the guarantee, the customer or distributor must send the monitor accompanied with the invoice to GeTeMed. GeTeMed will test the monitor. If no fault is discovered under the scope of this guarantee, than the purchaser takes responsibility for the costs of transport and testing. If GeTeMed decides to replace a defective device or part of it, then the ownership of the defective device or component is transferred to GeTeMed.
4. Intrusions and attempts to repair shall be executed only by GeTeMed or authorised third parties that have been certified to do so by GeTeMed. Any warrantee claim is void if such attempts by non-authorised persons have been performed. The warrantee is also void if the VitaGuard® monitor or its components have been improperly handled.

- Loss of the pulse signal can occur if the patient has hypotension, severe vasoconstriction, severe anaemia or hypothermia.
- Loss of pulse signal can occur if there is an arterial occlusion proximal to the sensor.
- Loss of pulse signal can occur if the patient is in cardiac arrest or is in shock.

Cleaning

- Disconnect sensors and cables from the patient and the monitor, before cleaning them. Use a damp cloth to clean both the monitor and the cables. Use cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not use aggressive solvents or cleaning agents such as petroleum-based or acetone solutions to clean the monitor. These substances attack the device's materials and device failure may result.
- Do not use alcohol to clean the monitor or cables as this hardens the cables.
- Do not touch, press or rub the display panel or casing with abrasive cleaning compounds, instruments, brushes, rough-surfaced materials, or bring them into contact with anything that could scratch them.
- Do not autoclave, pressure sterilise or gas sterilise the monitor or any of its components.

Regulatory information

- VitaGuard® VG 300 complies with the requirements of the Medical Device Directive 93/42/EEC.
- VitaGuard® VG 300 fulfils the EMC requirements laid out under the directive 89/336/EWG and EN60601-1-2 1/May 1993, part 1.2; EN55011 class B: 1991; DIN VDE 0875 part 11/07.92.
- VitaGuard® VG 300 is a class IIa devices according to the Medical Device Directive 93/42/EEC (MDD).

blood or tissue has ALWAYS a lower SpO_2 level these peaks are always at lower SpO_2 values.

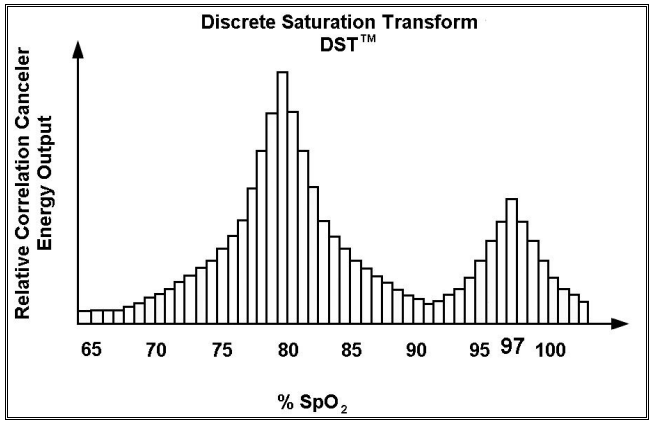

Fig. 15 DST plot of output power vs. SpO_2 value

In reverse, T**he arterial SpO_2 value is always given at the peat with the highest SpO_2.**

This entire sequence is repeated every 0.4 seconds on the most recent eight (can be varied between six and 16) seconds of raw data. The MS-3 SpO_2 therefore corresponds to a running average of arterial saturation of arterial haemoglobin saturation that is updated every 0.4 seconds.

Error codes

The Masimo SpO_2 module (MS-3 board) incorporated in VitaGuard® VG 300 communicates with VitaGuard® via a serial port. Should a failure occur on the module, an appropriate error code is passed to VitaGuard®. These codes are registered in the compliance log. Should no communication take place between VitaGuard® and the MS-3 module, then code 31 is registered.

Error code	Meaning
31	No communication with MS-3 board.
32	DSP: Checksum Failure.
33	DSP: Program Memory Test Failure.
34	DSP: Data Memory Test Failure.
35	DSP: Detector ADC Interrupt Failure.
36	DSP: MCU Interrupt Failure.

Error code	Meaning
37	DSP: Diag Queue Overrun.
38	DSP: Hardware Status Failure.
39	DSP: Raw (Data) Queue Overrun.
40	DSP: MCU Watchdog Failure.
63	Diagnostic Failure.

Tab. 10 Explanation of the error codes used within VitaGuard® VG 300.

These error codes are intended for maintenance purposes by qualified personnel only.

Patent information

The following is a (possibly incomplete) table of U.S. issued Patents and Applications and Patent Markings.

No	USA Patent	Tittle
1	5.337.744	Low Noise Finger Cot Probe
2	5.452.717	Low Noise Finger Cot Probe
3	5.482.036	Signal Processing Apparatus and Method
4	5.490.505	Signal Processing Apparatus
5	5.632.272	Signal Processing Apparatus
6	5.638.818	Improved Low Noise Optical Probe
7	5.645.440	Patient Cable Connector
8	5.685.299	Signal Processing Apparatus
9	5.758.644	Manual and Automatic Probe Calibration
10	5.769.785	Signal Processing Apparatus and Method
11	5.782.757	Low Noise Optical Probes
12	D393.830	Patient Cable Connector
13	5.823.950	Manual and Automatic Probe Calibration
14	pending	Improved Low Noise Optical Probe
15	pending	Patient Cable Connector
16	pending	Improved Signal Processing Apparatus
17	pending	Signal Processing Apparatus
18	pending	Shielded Medical Connector
19	pending	Signal Processing Apparatus
20	pending	Signal Processing Apparatus

Accuracy and factors effecting the SpO_2 measurement

- If you doubt the accuracy of any measurement, first check the patient's vital signs by alternate means and check that the monitor is functioning correctly.
- Inaccurate measurements may be caused by incorrect sensor application or use.
- Inaccurate measurements or loss of the pulse signal may be caused by exposure to excessive illumination such as surgical lamps (especially ones with Xenon light sources), bilirubine lamps, **fluorescent lights, infrared heating lamps, or direct sunlight**. Expose to excessive illumination can be corrected by covering the sensor with a dark or opaque material.
- Inaccurate measurements may be caused by placing the sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line.
- Loss of the pulse signal can occur if the LNOP® sensor is too tight.
- Use only Masimo LNOP® sensors for SpO_2 measurements. Other sensors may cause improper performance.

Information for the handling paediatrician

- A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analysed by a laboratory co-oximeter to completely understand the patients condition.
- Inaccurate measurements may be caused by significant levels of dysfunctional haemoglobin (e.g. Carboxyhaemoglobin or Methaemoglobin). Carboxyhaemoglobin may erroneously increase SpO_2 readings. The level of increase is approximately equal to the amount of Carboxyhaemoglobin present.
- Dyes (e.g. Indocyanine green or methylene blue) or any substance containing dyes that change the usual arterial pigmentation may cause erroneous readings or inaccurate measurements.
- Inaccurate measurements may be caused by venous pulsation

- **Electrical shock hazard:** Never open or tamper with the power adapter. Do not use the power adapter if it has fallen.
- Do not operate the power adapter from an electrical outlet controlled by a wall switch or dimmer.
- The mains power adapter should not be operated in damp environments (e.g. bathroom or utility room).
- Remove the batteries when storing the monitor for longer periods.
- You can check the battery status by pressing <INFO/△> multiple times. Please follow the procedure explained in 'Battery replacement' on page 22.

Safety precautions - Sensor and cable

- Only use the SpO_2 patient cable delivered with the monitor.
- Connect the SpO_2 sensor to the SpO_2 patient cable (PC08 or PC12) only.
- Only use Masimo SpO_2 sensors that have been verified and delivered by GeTeMed or its agents. Carefully read the sensors 'Directions for Use' information.
- Carefully route the cables to reduce the risk of patient entanglement or strangulation! If necessary, affix the cables with a plaster or tape.
- Tissue damage can be caused by incorrect application or use of an LNOP® sensor, for example, by wrapping the sensor too tightly. Inspect the sensor site as directed in 'Directions for use of LNOP® sensors' on page 50 to ensure skin integrity and correct positioning and adhesion of the sensor. Detailed instructions for the different sensor types are given for the LNOP® sensors DC1 on page 51, Adt on page 55, Pdt on page 59, Neo on page 64 and NeoPt on page 68.
- Do not use damaged LNOP® sensors or cables. Do not immerse in water, solvents or cleaning agents. Detach the sensor from the patient before bathing it.
- Do not attempt to sterilise by any means. Do not use alcohol to clean the cables as this may harden the cable isolation.

No	USA Patent	Tittle
21	pending	Method and Apparatus for Demodulating
22	pending	Manual and Automatic Probe Calibration
23	pending	Method and Apparatus for Demodulating
24	pending	Improved Signal Processing Apparatus
25	pending	Low Noise Optical Probes
26	pending	Signal Processing Apparatus and Method
27	pending	Signal Processing Apparatus
28	pending	Signal Processing Apparatus
29	pending	Photodiode Detector with Integrated Shielding
30	pending	Pulse Oximetry Sensor Adapter
31	pending	Non-Protruding Optoelectronic Lens
32	pending	Patient cable sensor Switch

Patent Marking: The Masimo-Device incorporated in VitaGuard® is covered under one or more of the following U.S.A. patents: 5.482.036, 5.490.505, 5.632.272, 5.685.299, 5.758.644, 5.769.785 and int. equivalents. U.S.A. and international patents pending.

Tab. 11 The most important patents on pulse oximetry issued in the U.S. for Masimo Corp.

External alarm unit EA1000

Operation

The external alarm unit can be connected to VitaGuard® to amplify the integrated alarm generator. It is intended for situations where your home is such that you may not hear the integrated alarm generator reliably.

Do not cover the speaker!

Verify in your actual situation, if you can hear a possible alarm, independently of what you are doing. Think of activities like housecleaning, watching TV etc.

Caution: Due to the extreme volume of EA 1000 you should leave it at least 3 m off your patient!

Make sure the alarm speakers of VitaGuard® or EA 1000 are not blocked by anything placed on them. **You cannot react properly to an alarm if you cannot hear it! Make sure you can react to an alarm within a few seconds!** Remember: **YOU, the caretaker, must react on an alarm!** The monitor cannot react for you! Refer also to 'EMERGENCY SITUATION' on page 1 and 'Operation' on page 8.

Function elements

The unit has a trimmer to regulate the alarm volume. Once it is connected to VitaGuard® using the cable supplied, it is automatically activated. The three light emitting diodes (LED's) on the unit have the following functions:

LED	Meaning
'Monitoring active' (green, flashing)	VitaGuard is activated and the EA 1000 is ready. **Green flashing = system status OK!** The flashing frequency is independent from the rhythm of the LEDs on VitaGuard®.
'Change batteries' (red, flashing)	The battery is weak and should be exchanged. The remaining capacity at start of flashing is typically sufficient for about two days. Pay attention to the polarity of the new battery!
'Alarm' (red, flashing)	The monitor generated an alarm. A loud flashing tone is generated, which volume can be varied within some limits.

If none of the LEDs are active, then the monitor is not switched on or there is no monitor connected at all.

Technical data

item	Value
Battery:	9 V Battery Alkaline Type 6LR61 or 6AM6
Connection cable:	7,5 m (standard)
Operation period:	On average about two month

Tab. 12 Technical data of the external alarm unit EA 1000.

Safety with the external alarm unit

- **Caution:** Keep the external alarm unit at least 3 m away from the patient to prevent damage from the high alarm volume of the EA 1000.
- Pay attention to the polarity when replacing the battery!
- **Caution:** Do not puncture the speaker because you could damage it.

This can easily happen if operated in a tent. If condensation accumulates, wait at least 2 hours before using the monitor.

- Keep the monitor away from devices that produce strong electromagnetic fields such as televisions, walkie-talkies, radio transmitters (as found in cordless telephones and paging transmitters, radio controlled toys, security equipment in many shops, wireless communication links for computers and peripherals, etc.), fluorescent lamps, microwave ovens and so on.
- Do not use VitaGuard® near MRI units (magnetic resonance imaging). Induced currents could potentially cause burns. Also, VitaGuard® may affect the MRI image and the MRI unit may affect the accuracy of the VitaGuard® readings.
- Do not operate in connection with HF-surgical equipment, defibrillators, TENS units or pacemakers. Should, however, the monitor still be connected to the patient during defibrillation, the readings may be inaccurate for a short period afterwards.
- While monitoring patients do not connect VitaGuard® to any devices (e.g. evaluating PC) other than those delivered with the monitor. Other devices may not have the required isolation and cause excessive leakage currents (>100uA) to flow through the patient. This may damage the patient and/or the monitor.
- Static electricity from fabrics (e.g. curtains or rugs) may cause damage to the patient and the monitor or may reduce the reliability of the monitoring function. Always touch the patient's bed or a wall before touching the patient or the monitor. Try to use fabric softener when washing the patient's clothes to reduce static electricity.
- Do not operate VitaGuard® when travelling by air. Switch the monitor off and remove the batteries before packing the monitor into your luggage. Pressure due to other luggage my otherwise switch the monitor on during the flight causing the monitor to generate a technical alarm.

Safety precautions - Power supply

- Only use the mains power adapter NA 2000-2 or the car power adapter NAK1500.

- **Electrical shock hazard:** Never open or dismantle the monitor or any other items delivered with the monitor e.g. mains power adapter, cable connectors, etc.
- Do not lift VitaGuard® by the power supply cord or any of the patient cables.
- Do not place VitaGuard® or its power adapter in a position that might cause it to fall onto the patient.
- Do not press heavily on the monitor (press buttons lightly).
- Do not use damaged components, sensors or cables.
- Do not immerse VitaGuard® or any of its components in liquids. Detach all sensors from the patient before bathing.

VitaGuard's MDD approval is bound to approved accessories!

- VitaGuard® and the authorised accessories can only be purchased through authorised agents. Order new sensors before you run out! Never use accessories from other sources!
- Maintenance repairs may only be carried out by authorised persons.
- Check the acoustic alarm on a weekly basis.
- If an alarm condition occurs while the alarm silence period is activated (e.g. after pressing a button), the only alarm indication is the visual red alarm LED.
- Send the monitor back to the manufacturer or agent for environmental friendly disposal.

Safety precautions - Environment

- Do not operate in the vicinity of explosive gases. Do not use in the presence of flammable anaesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.
- Do not use in extreme temperatures (below 10°C or above 40°C). Do not place VitaGuard® near heat sources such as radiators, ventilators, ovens, etc. and do not expose it to direct sunlight.
- Neither the monitor nor any of its accessories may be immersed into liquids. Detach the sensor from the patient before bathing it.
- Do not expose the monitor to sudden temperature or humidity variations. Humidity changes should not result in condensation accumulating on the monitor.

- Avoid penetration of moisture into the unit.

Pay also attention to the safety precautions for VitaGuard® on page 31ff! These precautions are valid for the external alarm also!

Car adapter NAK 1500

Operation

The car adapter NAK 1500 can be used to operate a VitaGuard® monitor from the 12V car supply. NAK 1500 is connected instead of the mains adapter NA 2000-2. It is fitted with a safety universal plug (DIN ISO 4165), that fits alternatively into the cigarette lighter or the normal car socket outlet. A green LED signalises operation from the car power.

Technical data

item	Value
Input	12 V car power supplies.
Output	+5V DC
max. current	600 mA
Operational temperature.	10 .. 50 °C (50 .. 122 °F)
Connectors:	VitaGuard®: 2pin socket Car: safety universal plug
Cable:	3 m

Tab. 13 Technical data of the Car adapter NAK 1500.

Safety with the adapter NAK 1500

- **Caution:** Operate only on 12V car power supplies!
- To avoid condensation, do not leave the car adapter in the car overnight.
- The car adapter can be fixed in the car with the attached Velcro tape. It should not be exposed to direct sunlight or warm air from the cars heating system.

VI. Directions for use of LNOP® sensors

Following you'll find help in deciding what type of sensor to use. Following, an adapted copy of the material accompanying every economy-sized package of different LNOP® sensors is printed.

Sensor selection

GeTeMed offers five different types of LNOP® sensors: LNOP®-DC1, LNOP®-Adt, LNOP®-Pdt, LNOP®-Neo and LNOP®-NeoPt.

Selection plan

Following you'll find a scheme that might help you to decide what type of sensor to choose:

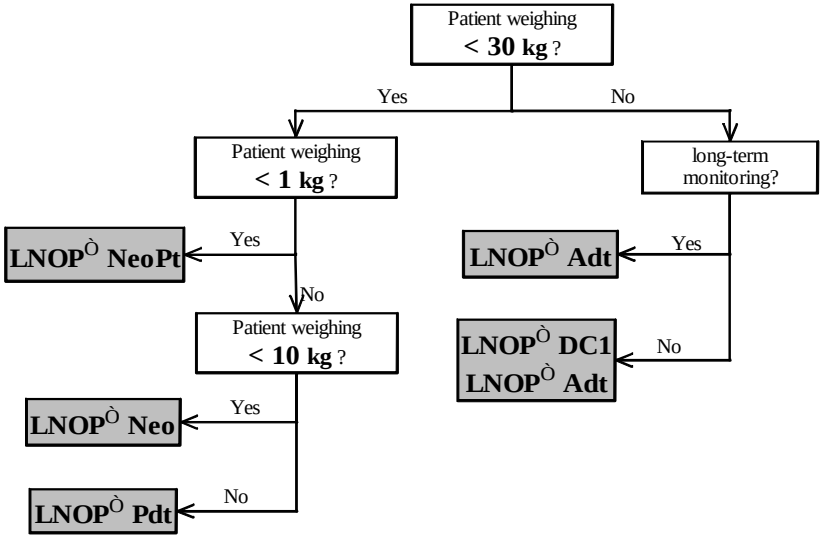

Fig. 16 Plan to choose the optimal sensor type.

After choosing the right sensor you may read the appropriate sensor instructions. You'll find the manuals for the LNOP® DC1 hereafter, for the LNOP® Adt on page 55, for the LNOP® Pdt on page 59, for the LNOP® Neo on page 64 and for the LNOP® NeoPt on page 68.

IV. Safety and Accuracy

Important – Intended Use:

VitaGuard® is designed to monitor pulse rate and oxygen saturation. Should a bradycardia alarm (low pulse rate) or a drop in the arterial oxygen saturation occur, then artificial respiration and cardiopulmonary resuscitation (CPR) measures may need to be taken. Therefore, allow a trained person to demonstrate to you how you should perform these measures..

Safety precautions

Safety precautions - Usage

YOU must act on alarms!

- **VitaGuard has no therapeutic intentions. <u>YOU,</u> the caregiver, must act in the event of an emergency.**
- **Never leave the patient alone until you have verified that the monitor is working properly!**
- Never continue operating a damaged or unreliable monitor! Immediately check the vital signs of the patient! Send the monitor back to the manufacturer or agent for inspection! Watch the patient yourself until you got another monitor or your handling physician advises you to stop monitoring.
- Verify that you can hear a possible alarm independent of where you are and what you are doing. Make sure that VitaGuard's alarm speaker is not blocked by anything laid on top of the monitor. **You cannot act promptly to an alarm if you do not hear it!**

Stay near your patient!

- **Make sure you can act on an alarm within a few seconds!**
- VitaGuard® must be demonstrated to you by a qualified person. Do not operate the monitor until you have been made familiar with its usage by a trained person and have read and understood this manual and all other documentation provided.

Important!

- Allow your doctor to set the alarm limits and monitoring parameters suitable for your patient.
- VitaGuard® may not be used for other purposes other than the intended purpose laid out in 'Intended use of VG 300' on page 5.

Pulse oximetry

Item	Value range
Pulse rate	25 – 240 BPM
Lower alarm limit	25, 30, 35, ... 175, 180 BPM
Upper alarm limit	100, 105, 110, ... 235, 240 BPM
Pulse rate accuracy: (± 1 Std. Dev.)*	± 3 digits during no motion conditions ± 5 digits during motion conditions
SpO_2 range	1 – 100 %
SpO_2 accuracy: (± 1 Std. Dev.)*	Range above 70 % - ± 3 digits on neonates during motion. Range 0 % - 69% unspecified

* Testing based on adult volunteers in induced hypoxia studies with LNOP®-Adt sensors in the range 70 – 100% SpO_2 against a laboratory co-oximeter and ECG monitor.

Tab. 7 Pulse rate monitor properties of VitaGuard® VG 300.

Miscellaneous

Item	Value range
MDD classification	IIa
Safety classification	BF (IEC 601-2-25) IP41 (IEC 601-1)
Operating temperature	10 - 40 Celsius
Humidity	0 – 90 %, non condensing

Tab. 8 Miscellaneous properties of VitaGuard® VG 300.

LNOP® DC1 - Directions for use

Fig. 17 Instructions for LNOP® DC1 SpO_2 sensors.

These sensors are intended for multiple use on different patients weighing > 30 kg. They are non sterile and latex free and can not be sterilised.

INDICATIONS/CONTRAINDICATIONS

The LNOP DC1, Reusable Adult Sensor is indicated for either "spot check" or continuous non-invasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for patients weighing >30 kg. It is for use only with instruments containing Masimo SET oximetry or licensed to use LNOP sensors. Consult individual instrument manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The LNOP DC1 is contraindicated for use on mobile patients or for prolonged periods of use. It is not intended for long-term monitoring. It must be removed and repositioned to a different monitoring site at least every four (4) hours. If extended monitoring is required, use of a LNOP Adt adhesive sensor is recommended.

INSTRUCTIONS

A) Site Selection

- Choose a site that is well perfused and least restricts a conscious patient's movements. The ring finger of the non-dominate hand is preferred.
- Alternatively, the other digits on the non-dominate hand may be used. Always choose a site that will completely cover the sensor's detector window. The great toe or long toe (next to the great toe) may be

used on restrained patients or patients whose hands are unavailable.

- Site should be cleaned of debris prior to sensor placement.

B) Attaching the Sensor to the Patient

1. Open the sensor by pressing on hinge tabs. Place the selected digit over the sensor window of the LNOP DC1. The fleshiest part of the digit should be covering the detector window in the lower half of the sensor. The top half of the sensor is identified by the cable. On finger sites, the tip of the finger should touch the raised digit stop inside the sensor. If the fingernail is long, it may extend over and pass the finger stop (Fig. 18).

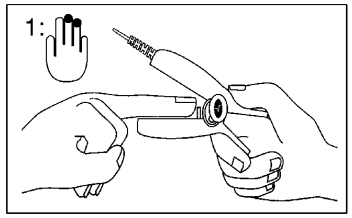

Fig. 18 DC1 sensor placement

2. The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger (Fig. 19). Check position of sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data.

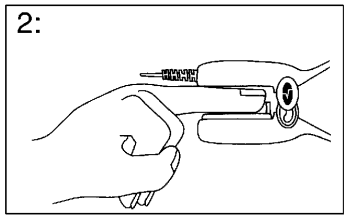

Fig. 19 Orientation of emitter and detector

3. Orient the sensor so that the cable will be running towards the top of the patient's hand (as shown in Fig. 20). Connect the LNOP DC1 connector to a patient cable.

III. Technical Data

General

Item	Value range
Weight	750g (with batteries)
Dimensions	(13,5 x 19 x 4,5) cm^3
Batteries	4 x 1,5 V (Type LR6, AA), alkaline
Battery operation	min. 2 hours* with SpO_2 monitoring
Key panel	Washable buttons
Battery indicator	Flashing message
Battery exhaustion	Warn tone
Mains supply	External power adapter NA 2000-2 with FRIWO FW1299 (5Volt, 900 mA, DC)
Display elements	LED's and LCD graphical display
Patient cable	Masimo patient cable PC08, length 2.44m
Test and maintenance period	A maintenance procedure is required every 18 months. The end of the maintenance period is marked with a sticker. 
* Only with batteries VARTA ALKALINE Extra Longlife!	

Tab. 5 General properties of VitaGuard® VG 300.

Memory

Item	Value range
Capacity	200 episodes
Duration	approx. 7 hours
Storage mode	Event or permanent
Pre-alarm storage	10 - 60 seconds
Post-alarm storage	10 - 60 seconds
Interface	RS232 interface
Software option	VitaGuard® for Windows – Software program for evaluation of stored data

Tab. 6 Memory properties of VitaGuard® VG 300.

Monitor log:

In **VitaGuard® for Windows** one can display an Overview over the monitoring period (Monitor log: (Fig. 13). Here the monitoring took place only during the night with short interrupts around midnight and in the early morning.

The main screen (Fig. 14) shows the context of the actual episode for the pulse frequency and the plethysmogram.

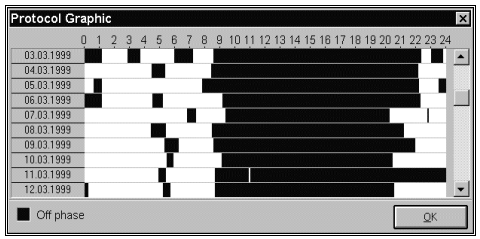

Fig. 13 VitaGuard® for Windows: Monitor protocol

Easy but complex documentation for the patient bulletin.

VitaGuard® for Windows supports the documentation of the monitoring behaviour and results. One can generate and print many overviews and tables.

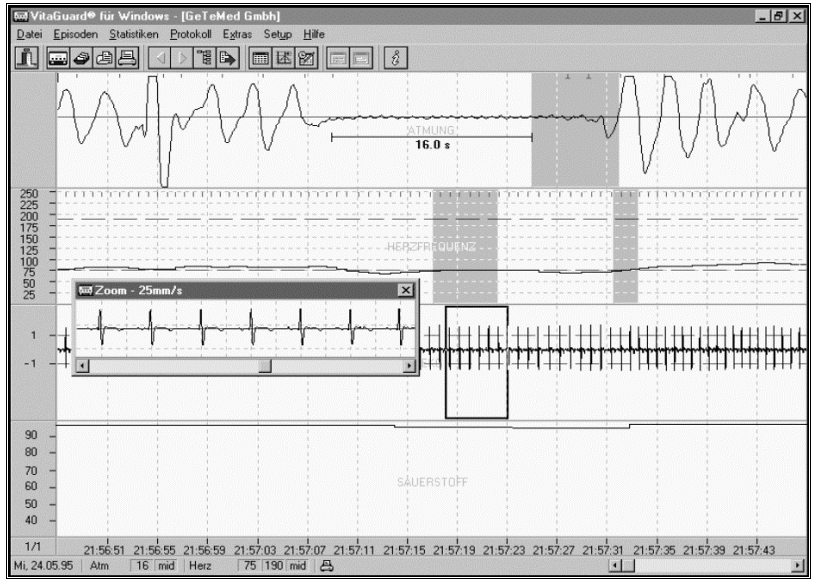

Fig. 14 Main screen of VitaGuard® for Windows; Bradycardia-episode

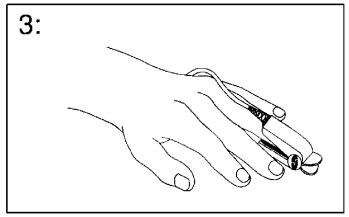

Fig. 20 Correctly attached sensor

NOTE: With smaller digits, in order to completely cover the detector window, the digit might not need to be pushed all the way to the stop. The sensor is not intended for use on the thumb or across a child's hand or foot.

C) Attaching the Sensor to the Patient Cable

1. Orient the connecting tab so that the "shiny" contacts are facing up and mate the logo to the logo on the patient cable (Fig. 21). Insert the LNOP DC1 connector over the patient cable connector until there is a tactile or audible click of connection.

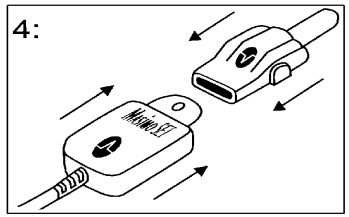

Fig. 21 Connecting patient cable and sensor

2. Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient for ease of movement.

D) Disconnecting sensor and patient cable

1. Place thumb and index finger on grey buttons on either side of the patient cable connector (Fig. 22).
2. Press firmly on the grey buttons and pull to remove the sensor.

CLEANING

To clean the sensor, first remove it from the patient and disconnect it from the patient cable. You my then clean the LNOP DC1 by wiping it with a 70% isopropyl alcohol pad. Allow the sensor to dry prior to placement on a patient.

Caution: Do not soak or immerse the cable in any liquid solution. Do not attempt to sterilise.

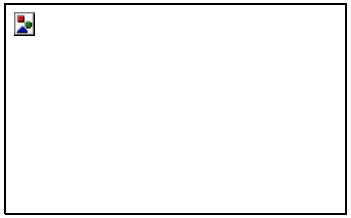

Fig. 22 Disconnecting patient cable and sensor

WARNINGS

- The site must be checked and changed at least every four (4) hours
  NOTE: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when sensors are not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilise.
- Intravascular dyes may lead to inaccurate SpO2 measurements.
- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO2 measurement.
- Elevated levels of Methaemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Failure to apply the LNOP DC1 properly may cause incorrect measurements.
- Do not use the LNOP DC1 during MRI scanning.
- Avoid placing the LNOP DC1 on any extremity with an arterial catheter or blood pressure cuff.
- The pulsation's from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against an ECG heart rate.
- Avoid bending and distorting the sensor cable, because this may damage the sensor.

Hint: If the monitor displays pulse rate and SpO_2 not constantly than check the sensor placement and reposition

Episode memory and PC interface

Integrated memory for 100 alarm episodes.

VitaGuard® is fitted with a solid-state memory for storing alarm episodes. The pulse rate, SpO_2 and plethysmograph are stored as a function of time. Up to approx. 7 hours of data (or 200 episodes) can be stored with the standard memory.

There are two storage modes possible - event mode or permanent mode. When, in event mode, an alarm occurs, both time and date as well as the signal curves for a programmable period prior to the alarm (usually 50s), during the alarm phase and for a programmable period after the alarm (usually 20s) are stored together as an alarm episode. In the permanent mode of operation, all the signals are continuously stored in blocks of approx. 2.5 minutes, regardless of whether an alarm occurs or not.

Event mode is default!

When the monitor is switched on, it always assumes event mode storage. To change to permanent storage mode, enter the expert mode and change the memory mode option under the 'System settings' menu. Refer also to 'System settings main menu:' on page 24.

In both modes, the memory operates as a loop memory i.e. when the memory is full (200 episodes), the oldest episodes are automatically deleted to make room for new ones. This ensures that the most actual stored episodes are available.

The actual memory usage is displayed during start-up of the monitor. It can be reviewed by pressing <INFO/△> multiple times.

Stored data can be reviewed on a PC.

The data from the monitor can be transferred to a standard PC over the serial RS232 interface and evaluated with a Windows based programme developed by GeTeMed. The PC programme can also be used to set the monitor internal clock

GeTeMed developed the Software **VitaGuard® for Windows** to support the evaluation of the saved protocols and alarm episodes. **VitaGuard® for Windows** runs on Windows 95, 98, NT 4.0 or higher. It is sold only to authorised dealers and to physicians that supervise users of **VitaGuard®.**

post-alarm period (usually 20s) to elapse before you can view the information about an alarm that has just occurred. The actual process of saving is displayed.

Alarm types

The following alarm types can be displayed under status information:

Bradycardia	Pulse rate below the set alarm limit.
Tachycardia	Pulse rate above the set alarm limit.
SpO_2 low	SpO_2 below the set alarm limit.
SpO_2 high	SpO_2 above the set alarm limit.
SpO2	Episode with an overrun of both SpO_2 limits.
Silent	Silent alarm where the SpO_2 lay outside either of the silent alarm limits.
Silent Brady.	Pulse rate below the silent alarm limit.
Silent Tachy.	Pulse rate above the silent alarm limit.
Permanent	Episode without an alarm stored in permanent mode.
Manual	Episode manually initiated.
Combination	Episode with more than one alarm cause e.g. SpO_2 and bradycardia together.

it, if necessary. If this does not help than change the sensor.

Hint: Sensors being used for a long period tend to reduced performance. A sensor should be replaced, if pulse rate and SpO_2 become questionable.

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules, using PC Series patient cabled, during no motion, the accuracy of the LNOP DC1 from 70% to 100% SpO2 is ± 2 digits (± 1 Std. Dev.).

Please see also 'Miscellaneous Warnings and Hints' **on page 73ff!**

LNOP® Adt - Directions for use

Fig. 23 Instructions for LNOP® Adt SpO_2 sensors.

These sensors are intended for multiple use on only one patient weighing > 30 kg. They are non sterile and latex free and can not be sterilised.

INDICATIONS/CONTRAINDICATIONS

The LNOP Adt, adult Adhesive Sensor is indicated for single-patient use for the continuous non-invasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for patients weighing >30 kg. The LNOP Adt is or use only with instruments containing Masimo SET oximetry or licensed to use LNOP sensors. Consult individual oximetry system manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The LNOP Adt is contraindicated for patients who exhibit allergic reactions to adhesive tape. The sensor must be removed and the site inspected at least every eight (8) hours and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

INSTRUCTIONS

A) Site Selection

- Choose a site that is well perfused and least restricts a conscious patient's movements. The ring or middle finger of the non-dominate hand is preferred.
- Alternatively, the other digits on the non-determinate hand may be used. Always choose a site that will completely cover the detector window. The great toe or long toe (next to the great toe) may be used on restrained patients whose hands are unavailable.
- The site should be cleaned of debris and dry prior to sensor placement.

B) Attaching the Sensor to the Patient

1. Open the pouch and remove the sensor. Holding the sensor with the printed side down, bend the sensor backward and remove the backing. Orient the sensor so the detector can be placed first (Fig. 24). Press the detector onto the fleshly part of the finger near the tip of the finger. Press down the "T" shaped adhesive ends of the sensor onto the finger (Fig. 25).

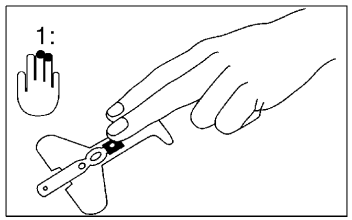

Fig. 24 Sensor placement; detector on the finger tip

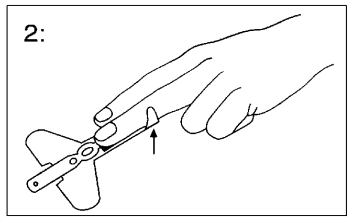

Fig. 25 Fixing of the detector

Time/Date main menu:

See also 'Explanation of the menu settings' on page 38!

These settings can be changed using <MODE/Esc>. Refer also to 'Monitor display structure' and 'Monitor menu structure' on pages 12 and 13. The different settings are explained in detail in 'Explanation of the menu settings' on page 38.

Item	Value range
Day (num.)	1, 2, ... 29, 30 (31).
Month	January, February, March etc.
Year	1998, 1999, etc.
Hour	0, 1, ... 22, 23.
Minute	0, 1, ... 58, 59.

Tab. 4 Value range for the time settings main menu

Status memory function

Using <STATUS/Enter>, the stored episodes can be examined in chronological order. By pressing the key once, information about the last stored episode is displayed. Using the arrow buttons, other episodes can be addressed. To obtain more information about a particular episode, press <STATUS/-Enter> again. After the alpha-numerical information you will see the stored signals. Press <MODE/Esc> to exit the episode information mode.

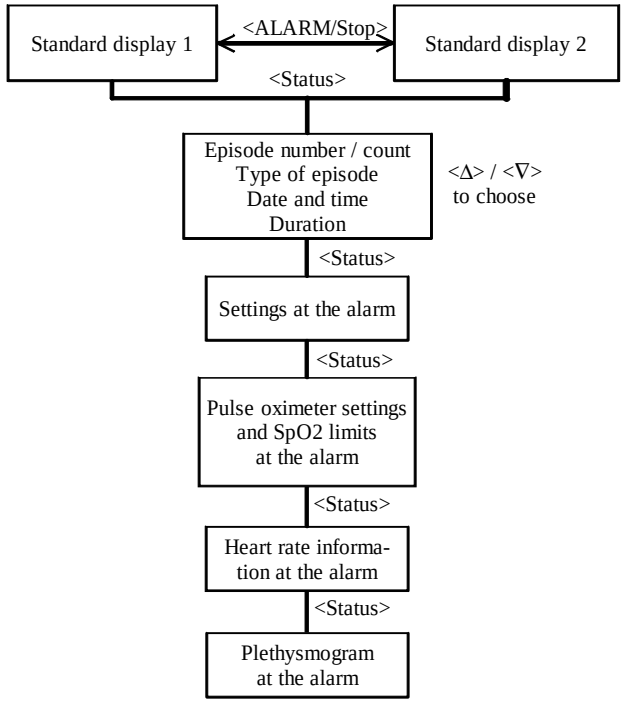

Fig. 12 Scheme on how to review stored data

Remember that you need to wait for the programmed

System settings main menu:

See also 'Explanation of the menu settings' on page 38!

These settings can be changed using <MODE/Esc>. Refer also to 'Monitor display structure' and 'Monitor menu structure' on pages 12 and 13. The different settings are explained in detail in 'Explanation of the menu settings' on page 38.

The factory defaults are shown in **large bold font**:

Item	Value range
Clear trends	**No** / yes
SpO_2 perfusion	Low_Perfusion On / L**ow_Perfusion Off**
SpO_2 average	6, **8** ... 14, 16 seconds
LCD power save	Off / **On**
LCD brightness	Level 1, 2, **3**, 4
Only available in expert mode:	
Wave display	Off / **On**
Silent alarms	**No** / Yes
Buzzer frequency	2048 Hz / **4096 Hz**
Delete memory	**No** / Yes
Pre-alarm time	10, 20, ... **50**, 60 seconds
Post-alarm time	10, **20**, ... 50, 60 seconds
Memory mode	**Event** / Permanent
Ring memory	No / **Yes**
Load defaults	**No** / Yes

Tab. 3 Value range for the items in the system settings main menu

Expert mode main menu:

See also 'Explanation of the menu settings' on page 38!

The expert mode can be activated using <MODE/Esc>. Refer also to “Monitor display structure” and “Monitor menu structure” on pages 12 and 13.

Item	Value range
Code word	Enter code word

2. Next, wrap the sensor with the emitter (*) and finger design over the fingernail and secure the wings down one at a time around finger (Fig. 26). When properly applied, the emitter and the detector should be vertically aligned as shown (Fig. 27). Check position of sensor to verify correct positioning and reposition if necessary. Complete coverage of the detector window is needed to ensure accurate measurements.

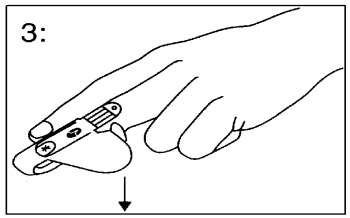

Fig. 26 Fixing of the emitter

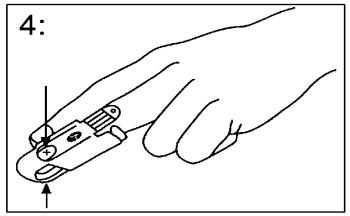

Fig. 27 Correctly attached sensor: emitter and detector are aligned!

3. The connector tab is now oriented on the top side of the patient’s finger so that the “shiny” contacts are facing up. Mate the logo on the sensor to the logo on the patient cable. Insert the patient cable into the sensor tab until there is a tactile or audible click of connection (Fig. 28). Gently tug on the connectors to ensure a positive contact. If required, tape may be used to secure the cable to the patient.

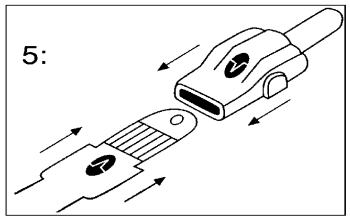

Fig. 28 Connecting patient cable and sensor

C) Reattachment

The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

NOTE: Prior to reattachment or rejuvenation, disconnect the sensor from the sensor cable.

- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol pad and allowing the sensor to thoroughly air dry prior to replacement on the patient.
- If the adhesive can not be adequately rejuvenated, use a new sensor.

D) Disconnecting Sensor and Patient Cable

1. Place thumb and index finger on grey buttons on either side of the patient cable (Fig. 29).

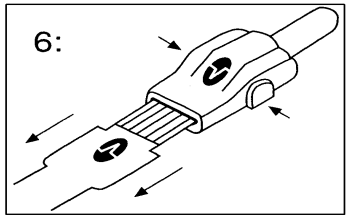

Fig. 29 Disconnecting patient cable and sensor

2. Press firmly on the grey buttons and pull to remove the sensor.

WARNINGS

- The site must be checked and changed at least every eight (8) hours
  NOTE: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when sensors are not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilise.
- Intravascular dyes may lead to inaccurate SpO2 measurements.

The monitor settings and stored alarm episodes are **not** lost when changing the batteries. Refer also to 'Technical Data' on page 29 for battery operation lifetime.

Mains adapter

Only use the mains adapter NA 2000-2 provided with the monitor. Other mains adapters may not fulfil the necessary safety standards and could cause serious damage to both the **patient** and the monitor. When VitaGuard® is operated from the mains adapter, the display backlight is automatically switched on.

Integrated menus

Monitor settings main menu:

See also 'Explanation of the menu settings' on page 38!

These settings can be changed using <MODE/Esc>. Refer also to 'Monitor display structure' and 'Monitor menu structure' on pages 12 and 13. The different settings are explained in detail in 'Explanation of the menu settings' on page 38.

The factory defaults are shown in **large bold font**:

Item	Value range
Lower HR limit	30, 35, ... **80**, ... 175, 180 BPM
Upper HR limit	100, 105, ... **220**, ... 255, 260 BPM
Lower SpO_2 limit	50, 51, ... **88** ... 99, 100 %
Upper SpO_2 limit	50, 51, ... 99, **100** %
only available in expert mode:	
Silent lower HR	**30**, 35, ... 50, ... 175, 180 BPM
Silent upper HR	100, 105, ... 255, **260** BPM
Silent lower SpO_2	50, 51, ... **88** ... 99, 100 %
Silent upper SpO_2	50, 51, ... 99, **100** %
Bradycardia delay	4, 5, **6**, ... 14, 15 seconds
Tachycardia delay	4, 5, ... **15**, ... 23, 24 seconds
SpO_2 lower delay	1, 2, ... **6**, ... 19, 20 seconds
SpO_2 upper delay	1, 2, ... **6**, ... 19, 20 seconds

Tab. 2 Value range for the items in the monitor settings main menu

fore, always insert batteries, even if you use the mains adapter supplied with the monitor.

Battery replacement

Switch the monitor off before replacing the batteries.

***Important!** Check batteries with active SpO_2 module!*

To test that the batteries in the battery compartment are charged enough for SpO_2 operation, carry out the follow steps:

- Remove the external power adapter so that the device is powered from batteries.
- Wait 30 seconds and then press <INFO/Δ> a number of times until you reach the battery information.
- If the state of the batteries is not good, replace them immediately with good-quality alkaline batteries such as VARTA alkaline Extra Longlife. It is recommended that you always keep at least two spare sets handy.

Replacing batteries:

Slide open the battery compartment at the back of the monitor. Pay attention to the polarity of the batteries when inserting the new ones(Fig. 11).

Please pay attention to the polarity of the batteries as shown on the bottom of the battery compartment.

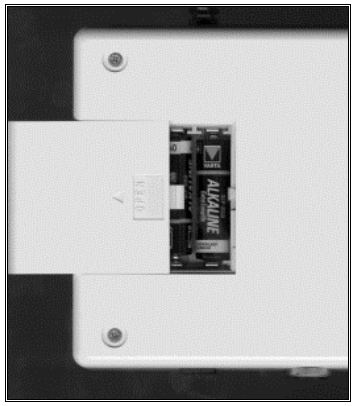

Fig. 11 Bottom of the monitor with partially opened Battery compartment.

GeTeMed recommends ALKALINE Extra Longlife Batteries.

Only use new, good-quality alkaline LR6 (AA) 1,5V batteries. Change the whole set of batteries. Never use new and old batteries together!

Hint:

Cheap non-alkaline batteries may lead to a drastic reduction in the battery operation time. Some batteries only have 10-15% of the capacity of good batteries.

- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO2 measurement.
- Elevated levels of Methaemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Failure to apply the LNOP Adt properly may cause incorrect measurements.
- Do not use the LNOP Adt during MRI scanning.
- Avoid placing the LNOP Adt on any extremity with an arterial catheter or blood pressure cuff.
- The pulsation's from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against an ECG heart rate.
- Avoid bending and distorting the sensor cable, because this may damage the sensor.

Hint: If the monitor displays pulse rate and SpO_2 not constantly than check the sensor placement and reposition it, if necessary. If this does not help than change the sensor.

Hint: Sensors being used for a long period tend to reduced performance. A sensor should be replaced, if pulse rate and SpO_2 become questionable.

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules, using PC Series patient cabled, during no motion, the accuracy of the LNOP Adt from 70% to 100% SpO2 is ± 2 digits (± 1 Std. Dev.).

Please see also 'Miscellaneous Warnings and Hints' **on page 73ff!**

LNOP® Pdt - Directions for use

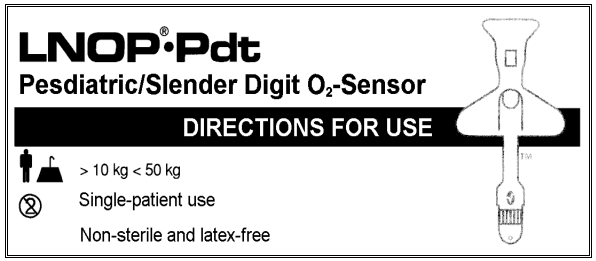

Fig. 30 Instructions for LNOP® Pdt SpO_2 sensors.

These sensors are intended for multiple use on only one patient weighing between 10 and 50 kg. They are non sterile and latex free and can not be sterilised.

INDICATIONS/CONTRAINDICATIONS

The LNOP Pdt, Paediatric/Slender Digit Adhesive Sensor is indicated for single patient use for the continuous non-invasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for patients weighing between 10 and 50 kg. It is for use only with instruments containing Masimo SET oximetry or licensed to use LNOP sensors. Consult individual instrument manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The LNOP Pdt is contraindicated for patients who exhibit allergic reactions to adhesive tape. The sensor must be removed and site inspected at least every eight (8) hours and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

INSTRUCTIONS FOR USE

A) Site Selection

- Choose a site that is well perfused and least restricts a conscious patient's movements. The ring or middle finger of the non-dominate hand is preferred.
- Alternatively, the other digits on the non-dominate hand may be used. Always choose a site that will completely cover the sensor's detector window. The great toe or second toe (next to the great toe) may be used on restrained patients or patients whose hands are unavailable.
- The site should be cleaned of debris and dry prior to sensor placement.

B) Attaching the Sensor to the Patient

1. Open the pouch and remove the sensor. Holding the sensor with the tan printed side downward, bend the sensor backward and remove the backing from the sensor. Orient the sensor so the detector can be placed first (Fig. 31). Press the detector onto the fleshly part of the finger near the tip of the finger. Press down the "T" shaped adhesive ends of the sensor onto the finger (Fig. 32).

Bear in mind that you should be able to reach your patient within 10 seconds in order to react promptly to a critical situation!

Battery operation

VitaGuard® can be operated either with four LR6 alkaline batteries or with an external power adapter (NA 2000-2 or NAK 1500; see 'Power supply' on page 6). The monitor also has an internal battery that always powers the internal memory and clock chip. Should the power adapter be suddenly removed from the monitor during operation and no batteries are installed, then the internal battery is used to generate a warn tone. This should be avoided!

Important Hint: The monitor must be returned to the manufacturer if the internal battery becomes weak.

Battery supervision

Once the installed batteries become weak, the monitor displays an appropriate message. This message is displayed after the initialisation phase when VitaGuard® is switched on and can be checked at any time using <INFO/Δ>. When the batteries become very weak, a message is repeatedly displayed for 2 seconds every 16 seconds informing you to replace them.

Attention: Monitoring is aborted when batteries are weak! If the external power adapter is not connected and the batteries become weak, the SpO_2 module is automatically switched off. The monitor generates a technical alarm to warn the clinician and displays an appropriate message. Once new batteries have been inserted into the unit or the external power adapter is reconnected, the SpO_2 module is automatically restarted and monitoring is continued. **Bear in mind, that without monitoring, critically situations may not be brought to your attention!** You should replace the batteries as soon as possible having seen the message on the display. **GeTeMed recommends that you always have at least two spare sets of batteries at hand!**

With low batteries you should firstly restore power supply! If the batteries are not replaced and are used further, the monitor will generate a technical alarm tone forcing you to replace the batteries (See Switching VitaGuard® on and off' on page 11).

Remember that the system can only operate in the event of a mains power failure if batteries are inserted. There-

ing of all settings is explained in 'Explanation of the menu settings' on page 38.

Alarms

YOU must react to alarms!

The monitor generates an alarm if the detected pulse rate falls for at least a given period below the lower limit or rises above the upper limit. Then the red LED flashes accompanied by a loud acoustic warning. The LCD displays a message about the actual type of alarm. The alarm can be stopped by pressing <ALARM/Stop>. **Go to your patient immediately and verify the situation!** Both the alarm setting and the alarm LED will flash in intervals of 1 second to indicate that an alarm has occurred. If no alarm occurs or if no button is pressed for 5 minutes, the standard display is deactivated and a message 'monitoring activated' will appear. The alarm LED will keep flashing to indicate that an alarm had occurred and will stop once <ALARM/Stop> is pressed. To obtain information about the alarm, press <STATUS/Enter>.

Should two alarms occur within the period of one minute, the alarm will not automatically cease. To stop the acoustic alarm, press <ALARM/Stop>.

System check

Alarm generator

Approximately 4 seconds after switching on the monitor, the monitor generates a short acoustic signal. Remember to listen for this tone each time you switch the monitor on. Should this signal not occur, return the monitor immediately to the manufacturer for inspection. Contact your supplier to get a replacement monitor. Never continue to use a faulty device!

Baby phone

Important Hint:

Before relying on any form of external system for transmitting the alarm tone to another room (e.g. Baby phone), ensure that the VitaGuard® alarm tone is transmitted clearly.

To amplify the alarm signal over a greater distance, we recommend that you use the external alarm unit EA 1000. This unit also checks that the monitor is switched on.

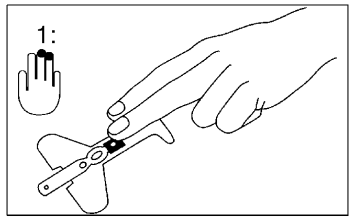

Fig. 31 Sensor placement; detector on the finger tip

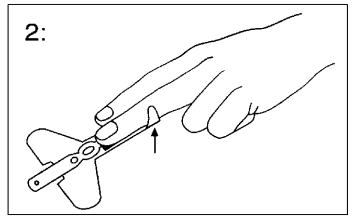

Fig. 32 Fixing of the detector

2. Next, wrap the sensor with the emitter (*) and finger design over the fingernail and secure the wings down one at a time around finger (Fig. 33). When properly applied, the emitter and the detector should be vertically aligned as shown in (Fig. 34). Check position of sensor to verify correct positioning and reposition if necessary. Complete coverage of the detector window is needed to ensure accurate measurements.

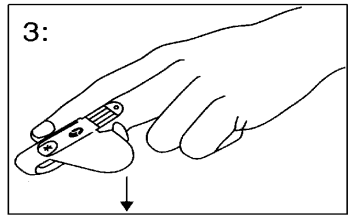

Fig. 33 Fixing of the emitter

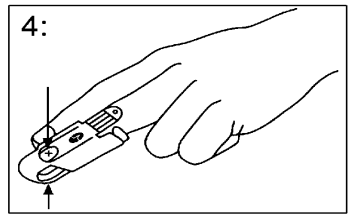

Fig. 34 Correctly attached sensor: emitter and detector are aligned!

3. The connector tab is now oriented on the top side of the patient's finger so that the "shiny" contacts are facing up. Mate the logo on the sensor to the logo on the patient cable. Insert the patient cable into the sensor tab until there is a tactile or audible click of connection (Fig. 35). Gently tug on the connectors to ensure a positive contact. If required, tape may be used to secure the cable to the patient.

C) ***Reattachment***

The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

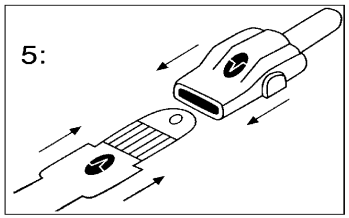

Fig. 35 Connecting patient cable and sensor

NOTE: Prior to reattachment or rejuvenation, disconnect the sensor from the sensor cable.

- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol pad and allowing the sensor to thoroughly air dry prior to replacement on the patient.
- If the adhesive can not be adequately rejuvenated, use a new sensor.

D) ***Disconnecting Sensor and Patient Cable***

3. Place thumb and index finger on grey buttons on either side of the patient cable (Fig. 36).
4. Press firmly on the grey buttons and pull to remove the sensor.

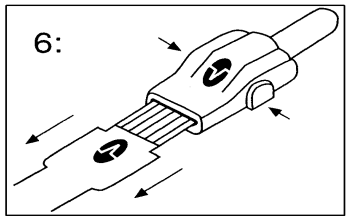

Fig. 36 Disconnecting patient cable and sensor

LED will flash in intervals of 1 second to indicate that an alarm has occurred.

Should two alarms occur within the period of one minute, the alarm will not automatically cease. To stop the acoustic alarm, press <ALARM/Stop>.

The upper alarm limit can be deactivated by setting the upper limit value to 100%.

Technical alarm and common reasons:

A technical alarm will be generated if the sensor is not properly connected to the monitor. In this case, a message is displayed telling the cause of the alarm. The SpO_2 value is zeroed out until the problem has been resolved. The main causes of technical alarms are:

- Bad positioning of the sensor (emitter and detector not placed across from each other).
- Sensor has fallen off the patient or the patient cable is not connected to the monitor.
- Excessive movement.
- Too much ambient light or electrical interference from an external source.
- Batteries are too weak for SpO_2 operation.

The LNOP®-sensors as well as the SET®-Technology are specially invented to handle those problematic situations. In normal domestic situations the most common source of technical alarms is bad sensor placement.

Pulse rate

Pulse rate alarm limits:

The standard pulse rate alarm limit settings are:

Lower limit: **80 BPM**

Upper limit: **220 BPM**

Important:

Those settings are suitable for children. When monitoring adults, consult your clinician for appropriate values. Do not change the alarm limits without prior consultation.

The selected values are displayed on the monitor LCD. If the pulse rate rises above the upper limit or falls below the lower limit, then an alarm will be generated. The delays before an alarm is generated are programmable. Generally, the upper limit needs to be exceeded for at least 15 seconds and the lower limit for at least 6 seconds before an alarm takes place.

For instructions on how to change the alarm parameters refer to 'Monitor display structure' on page 12. The mean-

Monitoring

Having connected the SpO_2 sensor and ensured that all connections are secure, switch on the monitor using the <ON/OFF>-button.

If problems arise you may reposition the sensor!

If false alarms occur you must check the sensor placement and the quality of the used sensor.
Do not change any alarm limits to combat alarms without prior consultation with your clinician!

Setting alarm parameters

Important:

Ask your doctor to set the alarm limits that suit the patient. Do not change the alarm limits without prior consultation.

SpO_2 parameters

SpO_2 alarm limits:

The standard SpO_2 alarm limits are:

Lower limit: **88 %**
Upper limit: **100 %**

To change the alarm limits, press <MODE> to enter the main menu structure. Select the 'Monitor settings' menu using <STATUS/Enter>. Move to the SpO_2 alarm limit menus with the arrow keys and select the required menu using <STATUS/Enter>. Remember to hold <ALARM/Stop> when selecting the new value. Press <STATUS/Enter> to accept the new value or <MODE/Esc> to reject. The limits may be adjusted between 50% and 100%. Refer to 'Monitor display structure' on page 12. The meaning of all settings is explained in 'Explanation of the menu settings' on page 38.

Should excessive false alarms occur, check that the sensor is properly connected. Allow a nurse or doctor to show you how to apply the sensor properly.

Alarms

***YOU must act** on alarms!*

If the displayed SpO_2 value falls below the lower alarm limit or rises above the upper alarm limit, VitaGuard® VG 300 will generate an alarm and display an appropriate message. You should go immediately to the patient and check its condition. If the SpO_2 value moves back within the set limits, the alarm will automatically cease. The exceeded alarm limit on the LCD display and the alarm

WARNINGS

- The site must be checked and changed at least every eight (8) hours
  NOTE: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when sensors are not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilise.
- Intravascular dyes may lead to inaccurate SpO2 measurements.
- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO2 measurement.
- Elevated levels of Methaemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Failure to apply the LNOP Pdt properly may cause incorrect measurements.
- Do not use the LNOP Pdt during MRI scanning.
- Avoid placing the LNOP Pdt on any extremity with an arterial catheter or blood pressure cuff.
- The pulsation's from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against an ECG heart rate.
- Avoid bending and distorting the sensor cable, because this may damage the sensor.

Hint: If the monitor displays pulse rate and SpO_2 not constantly than check the sensor placement and reposition it, if necessary. If this does not help than change the sensor.
Hint: Sensors being used for a long period tend to reduced performance. A sensor should be replaced, if pulse rate and SpO_2 become questionable.

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules, using PC Series patient cabled, during no motion, the accu-

racy of the LNOP Pdt from 70% to 100% SpO2 is ± 2 digits (± 1 Std. Dev.).

Please see also 'Miscellaneous Warnings and Hints' **on page 73ff!**

LNOP® Neo - Directions for use

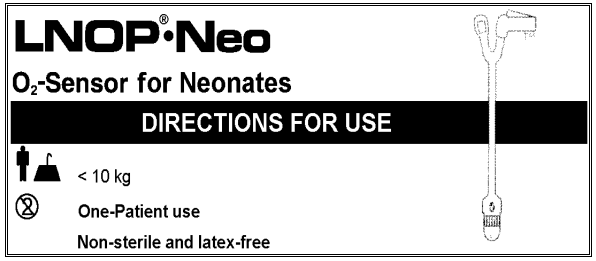

Fig. 37 Instructions for LNOP® Pdt SpO_2 sensors.

These sensors are intended for multiple use on only one patient weighing < 10 kg. They are non sterile and latex free and can not be sterilised.

INDICATIONS/CONTRAINDICATIONS

The LNOP Neo, Neonatal Adhesive Sensor is indicated for single-patient use for the continuous non-invasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for patients weighing < 10 kg (10,000 grams). The LNOP Neo is for use only with instruments containing Masimo SET oximetry or licensed to use LNOP sensors. Consult individual oximetry system manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The LNOP Neo is contraindicated for patients who exhibit allergic reactions to adhesive tape. The sensor must be removed and the site inspected at least every eight (8) hours and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

INSTRUCTIONS FOR USE

A) Site Selection

- Neonates: The preferred site is a foot. Alternatively, across the palm and back of the hand can be used. For

Attaching the sensor to the patient:

Detector on fleshy side of foot, hand, toe or finger!

- Open the sensor package and remove the sensor. Hold the sensor along the length of the 'Y' and remove the backing from sensor and bandage. Orient the sensor tail so that it is pointed away from the patient. Position the detector onto the fleshy part of the sole of the foot aligned with the fourth toe.

Emitter exactly on the opposite side! Wrap both with tape to fix it.

- Orient the emitter window on top of the extremity directly opposite to the detector. Wrap the bandage or plaster around to maintain proper alignment of detector and emitter windows. Check position of sensor to verify correct positioning and reposition if necessary. Complete coverage of the detector window is needed to ensure accurate data.

Connect sensor and cable properly and attach it to the child.

- Orient the connector tab to match the logos on the sensor tab and the patient cable. Insert the patient cable to the sensor tab until there is a tactile or audible click of connection. Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient for ease of movement.

Connecting the patient cable to VitaGuard®.

- By holding the connector of the patient cable so that the logo is pointing up, connect it to the VitaGuard® monitor. Again, an audible or tactile click will confirm connection. Gently tug on the connector to ensure a positive contact with the monitor.
  Avoid excessive bending of the patient cable!

The skin must be checked regularly!

The site should be checked at least every eight (8), on infants with poor skin integrity every two (2) hours, to ensure proper adhesion, skin integrity and alignment.

Use one of the adhesive sensors for long-term monitoring!

The LNOP®-DC1 sensor is not intended for long term monitoring. On patients with poor perfusion or when monitoring is needed for more than 8 hours don't use the DC1 sensor, but the appropriate adhesive sensor instead.

Disconnecting the sensor

Switch the monitor off before detaching the sensor!

Before you detach the sensor from the patient you should switch the monitor off and disconnect the sensor and the patient cable. Press firmly on the grey buttons on either side of the patient cable connector and pull to remove the sensor connector. Now you may detach the sensor from the patient.

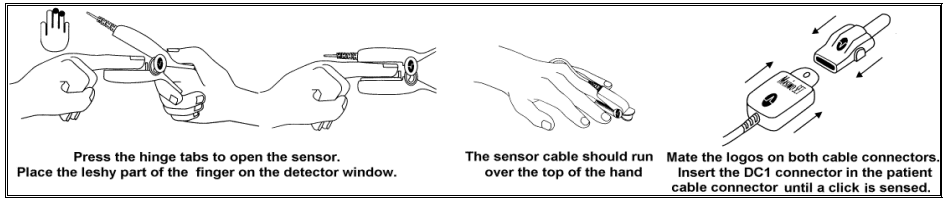

Fig. 6 Placing the LNOP®- DC1 SpO_2 sensors

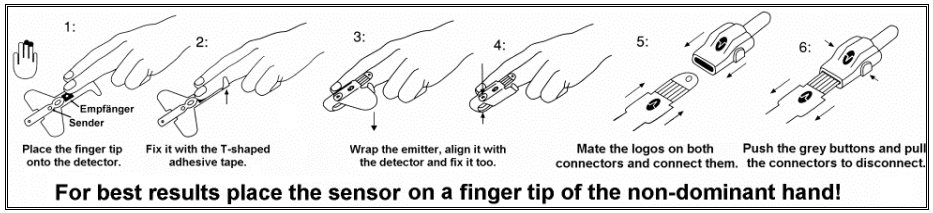

Fig. 7 Placing the LNOP®-Adt SpO_2 sensors

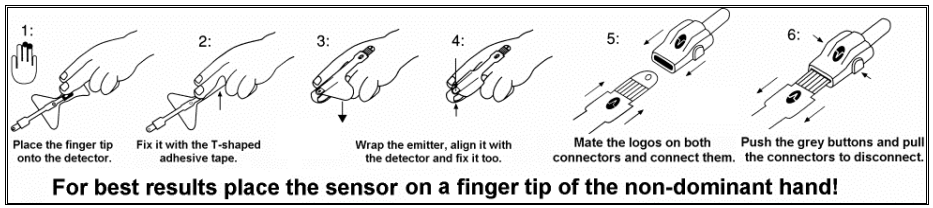

Fig. 8 Placing the LNOP®-Pdt SpO_2 sensors

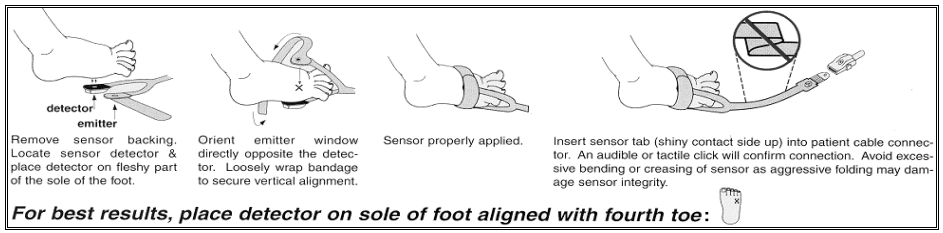

Fig. 9 Placing the LNOP®-Neo SpO_2 sensors

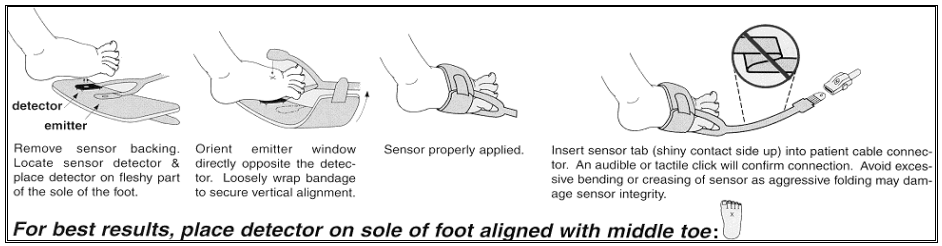

Fig. 10 Placing the LNOP®-NeoPt SpO_2 sensors

neonates with poor skin integrity, use of the LNOP NeoPt is recommended.

- Infants: For infants between 3 and 10 kg or with fat or oedematous feet, use of the LNOP Neo sensor on the big toe is recommended. Follow instructions shown with sensor detector on fleshy part (underside) of big toe. Alternative site would be the thumb.
- Paediatric patients: For infants or paediatric patients above 10 kg, use of the LNOP Pdt is recommended.
- Always choose a site that is well perfused and will completely cover the sensor's detector window.
- Site should be cleaned of debris and dry prior to sensor placement.

B) Attaching the Sensor to the Patient

1. Open the pouch and remove the sensor. Holding the sensor along the length of the "Y", remove the backing from the sensor and bandage. Orient the sensor tail so that it is pointed away from the patient. Position the detector onto the fleshly part of the sole of the foot aligned with the fourth toe (Fig. 38).

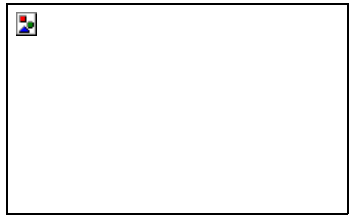

Fig. 38 Sensor placement; detector on the sole of the foot

2. Orient emitter window on top of foot directly opposite the detector. Wrap the bandage around the foot to maintain proper alignment of the detector and emitter windows (Fig. 39). Check position of sensor to verify correct positioning and reposition if necessary. Complete coverage of the detector window is needed to ensure accurate data (Fig. 40).

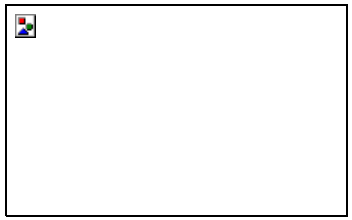

Fig. 39 Orientation of emitter and detector

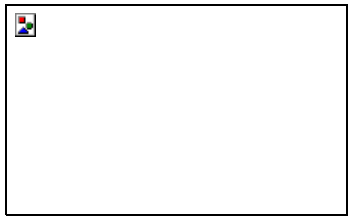

Fig. 40 Correctly attached LNOP® Neo Sensor

3. Orient the LNOP Neo's connector tab so that the top site of the "shiny" contacts are facing up. Mate the logo on the sensor tab to the logo on the patient cable. Insert the patient cable to the sensor tab until there is a tactile or audible click of connection (Fig. 41). Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient for ease of movement.

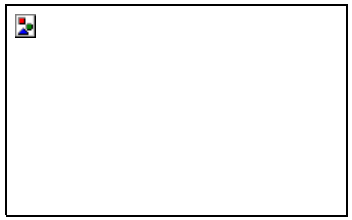

Fig. 41 Connecting patient cable and sensor

*C) **Reattachment***

The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

NOTE: Prior to reattachment or rejuvenation, disconnect the sensor from the sensor cable.

- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol pad and allowing the

Important: **The alarm is always deactivated for 20 seconds after pressing a button.**

Automatic storage of all parameters.

All monitor settings are stored and reappear automatically when the monitor is switched back on again. This is also true when replacing the batteries.

Alarm information

Alarms are shown in the display.

When an alarm occurs, a message related to the cause of the alarm appears on the display. <STATUS/Enter> can be used to obtain more information about the alarm. This information is available approx. 1 minute after the alarm has stopped.

Sensors

Handling LNOP®- sensors

Attention: Most sensors are 'Single-Patient'!

The LNOP®-sensors offered with VitaGuard® are disposable ones, intended for single-patient use and only with instruments containing Masimo SET® oximetry. They can be used several times, but prolonged use of the same sensor may lead to reduced performance if the sensor becomes dirty or the plaster no longer sticks properly. The only exception is the LNOP®-DC1 sensor, that can be used with different patients.

If you are not sure what type of sensor to choose, than read 'Sensor selection' on page 50. In the subsequent sections of 'Directions for use of LNOP® sensors' on page 50ff you'll find detailed instructions on how to use the different sensor types. Here the descriptions are limited to global instructions.

LNOP®-Neo-Sensors must be handled properly to achieve their full performance.

Before using a particular type of sensor, refer to the detailed instructions starting on page 50. Always choose a site that is well perfused and will completely cover the sensor's detector window. The skin should be dry and clean prior to sensor placement. For infants with poor skin integrity, use of the LNOP NeoPt is recommended.

Place the actual LNOP® sensor as shown in the appropriate figure. Use only sensors provided by GeTeMed or its authorised dealers.

Interrupted monitoring result in a vertical line in the trend curve!

The trend display shows a horizontal line if monitoring was interrupted. Such interrupts are typically caused by switching off the monitor.

***Important:** Clear the old trend curves when changing the patient!*

To display trend curves VitaGuard stores older data. When changing the patient, this could cause wrong data being used in the trend curves. **Clear the trend curves whenever you finally finish monitoring a specific patient!** More information on how to clear the trend curves can be found in “System settings main menu:” on page 24.

After displaying the last signal curve, the display reverts back to the selected standard display

Status (<STATUS/Enter>)

Information about stored episodes.

<STATUS/Enter> is used to view information on stored episodes. Once activated, the actual episode of interest can be selected with <INFO/Δ> and <GRAPHIC/∇>. Once the episode of interest is selected, the information about the episode can be viewed with <STATUS/Enter>. Each time it is pressed, a new page of information is displayed. Once the last page is reached, the plethysmograph curves can be viewed.

Changing parameters

Important – Controls protection!

Select the parameter that needs to be modified using the arrow buttons <INFO/Δ> or <GRAPHIC/∇>. Enter the selected parameter by pressing <STATUS/Enter>. By keeping <ALARM/Stop> pressed, use the arrow buttons to move the cursor to the required position. Once selected, accept the value by pressing <STATUS/Enter>. To leave the menu structure and reject any changes made, press <MODE/Esc>.

Safety measure:

Note that parameters can only be changed by simultaneously pressing <ALARM/Stop>. This is necessary to avoid any parameters from being unintentionally changed by siblings or small children or due to lightly touching or rubbing the monitor. Also remember that the buttons need to be held pressed for approximately ½ a second before they react. If any button is pressed for > 120 seconds (depending on the button), an acoustic warning is generated. This feature ensures that the alarm function cannot be deactivated by placing a heavy object on the monitor or if a key becomes defect.

sensor to thoroughly air dry prior to replacement on the patient.

- If the adhesive can not be adequately rejuvenated, use a new sensor.

D) Disconnecting Sensor and Patient Cable

1. Place thumb and index finger on grey buttons on either side of the patient cable (Fig. 42).
2. Press firmly on the grey buttons and pull to remove the sensor.

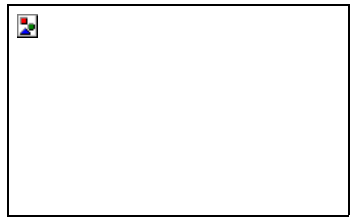

Fig. 42 Disconnecting patient cable and sensor

WARNINGS

- The site must be checked and changed at least every eight (8) hours
  NOTE: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when sensors are not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the sensor is damaged in any way, discontinue use immediately.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilise.
- Intravascular dyes may lead to inaccurate SpO2 measurements.
- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO2 measurement.
- Elevated levels of Methaemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Failure to apply the LNOP Neo properly may cause incorrect measurements.
- Do not use the LNOP Neo during MRI scanning.
- Avoid placing the LNOP Neo on any extremity with an arterial catheter or blood pressure cuff.

- The pulsation's from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against an ECG heart rate.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- Circulation distal to the sensor site should be checked routinely.
- Avoid bending and distorting the sensor cable, because this may damage the sensor.

Hint: If the monitor displays pulse rate and SpO_2 not constantly than check the sensor placement and reposition it, if necessary. If this does not help than change the sensor.

Hint: Sensors being used for a long period tend to reduced performance. A sensor should be replaced, if pulse rate and SpO_2 become questionable.

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules, using PC Series patient cabled, during no motion, the accuracy of the LNOP Neo from 70% to 100% SpO2 is ± 3 digits (± 1 Std. Dev.).

- **Please see also** 'Miscellaneous Warnings and Hints' **on page 73ff**

LNOP® NeoPt - Directions for use

Fig. 43 Instructions for LNOP® NeoPt SpO_2 sensors.

These sensors are intended for multiple use on only one patient weighing < 1 kg and having poor skin integrity.

Monitor menu structure

The monitor possesses three menu levels. The first menu level is activated with <MODE/Esc>. Use <INFO/Δ> or <GRAPHIC/∇> to highlight the required selection. To enter the selected menu, press <STATUS/Enter>.

Settings (<Modus>)

Configuration of the monitor.

There are four submenus available, that can be selected with <INFO/△> or <GRAPHIC/▽> and activated with <STATUS/Enter>:

- **Monitor settings:** All parameters governing alarm limits, settings and signals are grouped here.
- **System settings:** These include parameters such as scaling the displayed waves, power-save mode and settings for the SpO_2 monitor.
- **Time/Date:** The time and date of the internal clock can be adjusted using this menu.
- **Expert mode:** The expert mode can be activated upon entering a password. When activated, the 'Monitor Settings' menu and the 'System Settings' menu are extended to include functions primarily designed for clinicians e.g. activation of silent alarms and settings controlling the data memory.

Upon entering one of these menus, the parameter of interest can be selected using <INFO/Δ> or <GRAPHIC/∇>. Once highlighted, the individual menu can be entered by pressing <STATUS/Enter>.

Info (<INFO/△>)

Information about the monitor settings.

Information about the monitor settings, cardio and SpO_2 settings, as well as battery and memory information can be viewed by pressing this key. Each time it is pressed, a new information window appears. After displaying all available information, the display reverts back to the selected standard display.

Graphic (<GRAPHIC/▽>)

Signal curves and trends.

By pressing this key you can review the plethysmograph signal curves and some trend curves. The trends of pulse rate and SpO_2 are shown for the last 2.5 or 25 minutes, or the last 2.5 or 24 hours.

Pressing <ALARM/Stop> rewrites the trend display.

VitaGuard® can only be switched off using the key panel.

Always switch the monitor off using the key panel. Do not try to switch it off by unplugging the power adapter as this will only cause VitaGuard® to switch to battery mode. If, however, batteries are not inserted, an acoustic warning will be generated, which can only be deactivated by reinserting the power adapter and switching the monitor back on. Once the monitor has been switched off properly, you may remove the power adapter.

***Important:** Self tests are performed at start to ensure functionality*

After power is applied to the monitor, a series of tests are performed. The monitor type and the battery condition is displayed. All the LED's are activated and a short acoustic alarm is generated to verify that the alarm speaker operates correctly. **Should this acoustic signal not be generated, send the monitor for inspection to the manufacturer immediately.**

Monitor display structure

Monitor information can be viewed using the four buttons <MODE/Esc>, <INFO/Δ>, <GRAPHIC/∇> and <STATUS/Enter> as shown in Fig. 5. The four main menu paths will be explained next. For information on the individual monitor settings, refer to 'Explanation of the menu settings' on page 38ff.

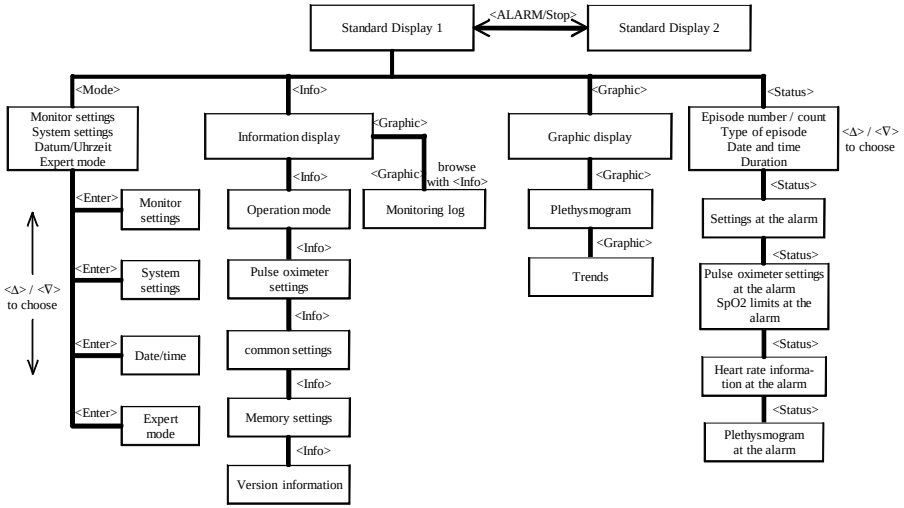

Fig. 5 Menu structure of VitaGuard® VG 300

They are non sterile and latex free and can not be sterilised.

INDICATIONS/CONTRAINDICATIONS

The LNOP NeoPt, Neonatal Adhesive Sensor is indicated for single-patient use for the continuous non-invasive monitoring of arterial oxygen saturation (SpO2) and pulse rate for patients weighing < 1 kg (1,000 grams), and with poor skin integrity. The LNOP NeoPt is for use only with instruments containing Masimo SET oximetry or licensed to use LNOP sensors. Consult individual oximetry system manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The LNOP NeoPt is contraindicated for patients who exhibit allergic reactions foam rubber products and/or adhesive tape.. The sensor must be removed and the site inspected at least every eight (8) hours and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

INSTRUCTIONS FOR USE

A) Site Selection

- The preferred site is a foot. Alternatively, across the palm and back of the hand can be used.
- Always choose a site that is well perfused and will completely cover the sensor's detector window.
- Site should be cleaned of debris and dry prior to sensor placement.

B) Attaching the Sensor to the Patient

1. Open the pouch and remove the sensor. Holding the sensor along the length of the "Y", remove the backing from the sensor. Orient the sensor tail so that it is pointed away from the patient. Position the detector onto the fleshly part of the sole of the foot aligned with the middle toe (Fig. 44).

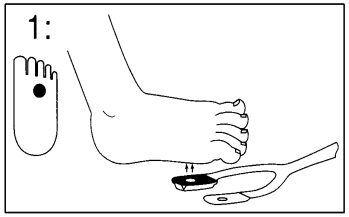

Fig. 44 Sensor placement; detector on the sole of the foot

2. Orient emitter window on top of foot directly opposite the detector. Wrap the sponge wrap around the foot with the white detector fitting into the pre-punched opening on the foam wrap. Be careful to maintain proper alignment of the detector and emitter windows and attach the 'Velcro' strap to secure (Fig. 45)! Check position of sensor to verify correct positioning and re-position if necessary. Complete coverage of the detector window is needed to ensure accurate data (Fig. 46).

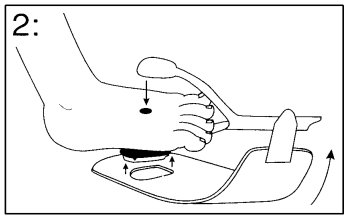

Fig. 45 Orientation of emitter and detector

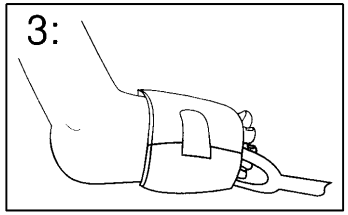

Fig. 46 Correctly attached LNOP® Neo Sensor

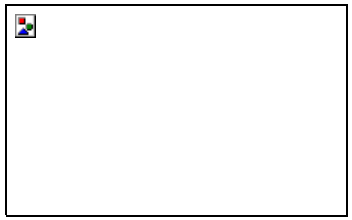

Fig. 47 Connecting patient cable and sensor

Standard Display 3 (power-save mode)

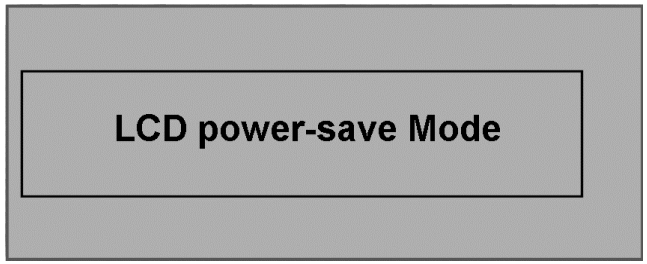

Fig. 4 Standard Display 3 (power-save mode)

Standard Display 3

This mode just indicates that the patient is being monitored and reverts automatically back to standard display 1 or 2 when an alarm occurs or a button is pressed. This mode is recommended for home use.

To switch between standard display 1 and 2, press <ALARM/Stop>. Display 3 appears automatically after 5 minutes if no button is pressed and the power-save setting is activated. See also 'System settings' on page 39

II. Operating VitaGuard®

Operation

Attention! Read 'Safety and Accuracy' on page 31!

Before using VitaGuard® for the first time, read and understand this manual carefully. Pay particular attention to “Safety precautions” on page 31ff. If you have questions about monitoring, handling VitaGuard® or how to react in the event of an emergency, **ask your clinician or monitor dealer!**

Switching VitaGuard® on and off

VitaGuard® is switched on using <ON/OFF>. To switch the monitor off, press <ON/OFF> for a couple of seconds and follow the instructions on the monitor display. After switching the monitor off, wait at least two seconds before switching it back on again.

Standard Display 1 (numbers and alarm limits)

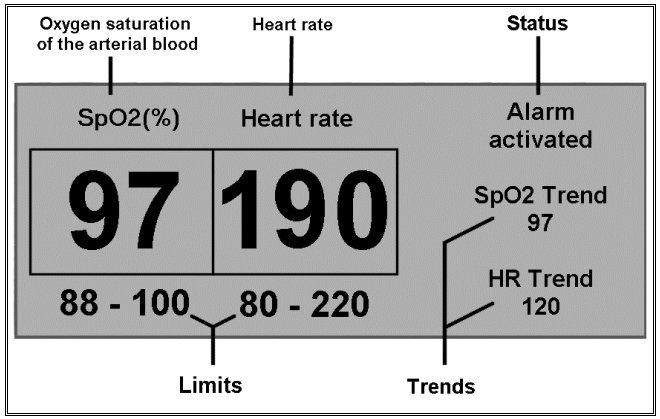

Fig. 2 Standard Display 1 (only numbers)

Standard Display 1: This display mode gives an overview of the measured values along with the associated alarm limits.

Standard Display 2 (graphic and numbers)

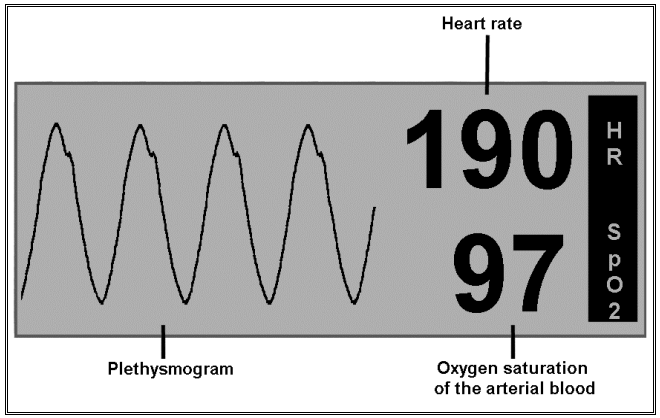

Fig. 3 Standard Display 2 (graphic and numbers)

Standard Display 2: The measured values for pulse rate and SpO_2 are also shown in this mode. The graphical part of the display shows the plethysmograph, thus giving a good indication of the condition of the patient and the placement of the SpO_2 sensor.

3. Orient the connector tab so that the “shiny” contacts are facing up. Mate the logo on the sensor tab to the logo on the patient cable. Insert the patient cable into the sensor tab until there is a tactile or audible click of connection (Fig. 47). Gently tug on the connectors to ensure a positive contact.

C) Reattachment

The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

NOTE: Prior to reattachment or rejuvenation, disconnect the sensor from the sensor cable.

- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol pad and allowing the sensor to thoroughly air dry prior to replacement on the patient.
- If the adhesive can not be adequately rejuvenated, use a new sensor.

D) Disconnecting Sensor and Patient Cable

1. Place thumb and index finger on grey buttons on either side of the patient cable (Fig. 48).
2. Press firmly on the grey buttons and pull to remove the sensor.

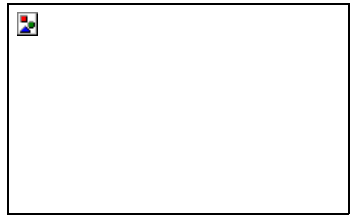

Fig. 48 Disconnecting patient cable and sensor.

WARNINGS

- The site must be checked and changed at least every eight (8) hours
  NOTE: Exercise extreme caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when sensors are not frequently moved. Assess the site at least every two (2) hours with poorly perfused patients.
- If the sensor is damaged in any way, discontinue use immediately.

- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilise.
- Intravascular dyes may lead to inaccurate SpO2 measurements.
- Elevated levels of Carboxyhaemoglobin (COHb) may lead to inaccurate SpO2 measurement.
- Elevated levels of Methaemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
- Failure to apply the LNOP Neo properly may cause incorrect measurements.
- Do not use the LNOP Neo during MRI scanning.
- Avoid placing the LNOP Neo on any extremity with an arterial catheter or blood pressure cuff.
- The pulsation's from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against an ECG heart rate.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- Circulation distal to the sensor site should be checked routinely.
- Avoid bending and distorting the sensor cable, because this may damage the sensor.

Hint: If the monitor displays pulse rate and SpO_2 not constantly than check the sensor placement and reposition it, if necessary. If this does not help than change the sensor.

Hint: Sensors being used for a long period tend to reduced performance. A sensor should be replaced, if pulse rate and SpO_2 become questionable.

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors or with licensed Masimo SET pulse oximetry modules, using PC Series patient cabled, during no motion, the accuracy of the LNOP Neo from 70% to 100% SpO2 is ± 3 digits (± 1 Std. Dev.).

Please see also the following section!

Key	Explanation
	Key to enter and exit the menu structure
	View operating mode View monitor settings View measurements View memory settings
	View plethysmogram and trends
	View stored episodes Accept new values when changing parameters
	Alarm stop Controls protection button Change between standard display 1 and 2
	Monitor on/off This key needs to be pressed for a couple of seconds. Follow the instructions on the LCD display.

Tab. 1 Key function in VitaGuard® VG 300

In the following sections keys to be pressed will be written in brackets, for example, <MODE/Esc> means that the mode button must be pressed. All buttons need to be pressed for approximately ½ a second before they react.

Connectors of VitaGuard® VG 300

VitaGuard® VG 300 (Fig. 1) has connectors to accommodate an external power adapter, the SpO_2 sensor cable and the external alarm amplifier EA 1000. A PC connector is also available to download data.

Only use cables and sensors delivered by GeTeMed or an authorised distributor.

Important: Use only the external power adapters delivered by GeTeMed!

For safety reasons, only use the mains adapter delivered with the monitor or the car power adapter NAK 1500. Under no circumstances should you connect any other mains adapter or connect the monitor with the 220V mains supply directly.

Failure to comply with the above advice may result in serious health damage or even death.

Monitor displays

VitaGuard® offers three standard display modes as follows:

Operation

Particularly easy operation.

Operation of VitaGuard® can be learned within minutes. Allow your doctor to demonstrate the monitor to you and to set the alarm limits to suit the patient being monitored.

*VitaGuard® is just a tool. **YOU must react!***

Remember that **YOU, the caregiver, must act in the event of emergencies.** Refer to 'Emergency situation' on page i.

In the home environment verify that you can hear the alarm, independent of where you are and what you are doing, for example, when house cleaning, watching TV, listening to radio, shopping, etc.

Caution: Do not cover the speaker!

Make sure VitaGuard®'s alarm speaker is not blocked by anything placed on the monitor. **You cannot react properly to an alarm if you cannot hear it! Make sure you can react to an alarm within a few seconds!**

Key panel

The key panel (Fig. 1) consists of six keys. These keys are explained in Tab. 1 below:

SpO_2-sensor | PC connector | ext. mains adapter | ext. alarm unit

Fig. 1 Frontal view and connectors of VitaGuard® VG 300

Miscellaneous Warnings and Hints

INSTRUMENT CAPABILITY

LNOP® sensors are intended for use only with instruments containing Masimo SET oximetry or pulse oximetry monitors licensed to use LNOP® sensors. Each sensor is designed to operate correctly only on the pulse oximetry systems from the original instrument manufacturer. Use of this sensor with other instruments may result in no or improper performance.

LICENSE

Purchase or possession of this sensor confers no expressed or implied license to use the sensor with any device which is not an authorised device or separately authorised to use LNOP sensors.

Order of a physician

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Miscellaneous

U.S.A. Patient 5,638,818 and international equivalents. Other U.S.A. and international patents pending.

Masimo SET technology under license from Masimo Corporation.

Manufactured in the U.S.A.

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become weak.

ule will automatically switch off when the batteries become too weak. The monitor generates an appropriate technical alarm to warn the childminder or clinician. To reactivate the SpO_2 monitor, either replace the batteries or power the device with the external power adapter supplied. Once the batteries have been replaced or the power adapter has been connected, the SpO_2 module switches back on automatically. **Remember that monitoring ceases once the SpO2 module switches off.**

Always have fresh batteries in the monitor!

When operating VitaGuard® VG 300 with the external power adapter, always ensure that fresh batteries are installed. If no batteries are installed, the monitor displays a message every 16 seconds informing you to do so. The batteries are important to ensure that the device can automatically switch to battery mode in the event of a mains power failure or when somebody abruptly removes the power connector. Should either of these events happen and no batteries are inserted, the monitor generates a permanent alarm tone. This can only be deactivated by inserting batteries into the device or reapplying the power connector and switching the monitor back on.

You should react promptly in the event of such an alarm because your child is no longer being monitored. This alarm tone is generated by an internal buffer battery. If this battery becomes weak, the monitor must be returned to the manufacturer for replacement

***Important!** Check batteries with active SpO_2 module!*

To test that the batteries in the battery compartment are charged enough for SpO_2 operation, carry out the follow steps:

– Remove the external power adapter so that the device is powered from batteries.
– Wait 30 seconds and then press <INFO/Δ> a number of times until you reach the battery information.

If the batteries are weak replace them immediately with good-quality alkaline batteries such as VARTA alkaline Extra Longlife. It is recommended that you always keep at least two spare sets handy.

Display

The large surfaced LCD display and the light emitting diodes (LED's) allow visual control of the monitor. Acoustic signals synchronous with the pulse rate may be activated using the key panel.

Sensors

LNOP®-Neo Sensors for pulse oximetry, e.g. monitoring of pulse and SpO_2.

The LNOP® Neo sensor delivered with the VitaGuard® VG 300 monitor is a single-patient disposable sensor intended to measure the functional oxygen saturation of arterial haemoglobin (SpO_2) of neonatal patients weighing less than 10 kg. To monitor premature born babies with very fragile skin use the LNOP®-NeoPt sensor with reduced adhesive area. For larger children between 10 and 50 kg use the LNOP®-Pdt sensor and for patients weighing more than 30 kg use the LNOP®-Adt sensor. Patients exhibiting allergic reactions to adhesive tape may not be able to use these sensors.

Important:

The sensor must be removed and the site inspected at least every eight (8) hours (every four (4) hours with DC1 sensor, every two (2) hours on children with poor skin integrity) and, if indicated by circulatory condition or skin integrity, reapplied to a different monitoring site.

Sensor application

The optimal SpO_2-sensor position depends on the sensor type and the patients weight!

The sensors delivered with VitaGuard® can be placed on the feet or hands of smaller children, on the big toe or thumb of larger children or on a finger of adult or paediatric patients. In choosing the actual site, you have to consider the necessity of obtaining a good signal and the comfort of the child. See also Directions for use of LNOP® sensors' and 'Sensor selection' on page 50ff.

The sensor must be fixed at its site without obstructing the blood flow.

Important: Cable routing!

Carefully route the patient cable to prevent strangulation. If necessary route the cable within the clothing and fix it with a plaster.

Power supply

Automatic switching between battery and mains supply.

VitaGuard® offers a high level of electrical safety and flexibility and operates with batteries, the car power adapter NAK 1500 or with the mains supply adapter NA 2000-2 provided. When an external power adapter is connected, the LCD backlight is automatically switched on. The monitor switches automatically to battery mode in the event of an external power failure. It is therefore strongly recommended that you always keep batteries in the monitor, even when using external power adapters.

Alarm when batteries

When operating the device with batteries, the SpO_2 mod-

modification, reproduction, release, performance, display or disclosure of the software (including the related documentation) by the U.S. Government or any of its agencies shall be govered solely by the terms of this Agreement and shall be prohibited except to the extend permitted by the terms of this agreement.

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TÜV

Genehmigung
Richtlinie 93/42/EWG Anhang II, Artikel 3
vollständiges Qualitätsmanagementsystem
Medizinprodukte

Registrier Nr.: HD 9911907 01

Bericht Nr.: C 9912944 E 02

Hersteller: GeTeMed Gesellschaft für
Technische Medizin mbH
Oderstraße 59
D 14513 Teltow

Geltungsbereich: Entwicklung, Herstellung, Vertrieb und Service von EKG- und Atmungs-Monitoring-Systemen

Produkte: siehe Anlage

Gültig bis: 12.08.2003

Hiermit genehmigt die "Benannte Stelle" das vom Hersteller eingeführte und angewandte Qualitätsmanagementsystem. Die Anforderungen des Anhanges II, Artikel 3 der Richtlinie werden erfüllt. Der Hersteller unterliegt der EG-Überwachung nach Anhang II Artikel 5 der Richtlinie. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner Herstellerkonformitätserklärung zu verwenden.

Zertifizierungsstelle

TÜV Rheinland Product Safety GmbH – Zertifizierstelle – TÜV Rheinland

Köln, den 06.12.1999

Dipl.-Ing. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Akkreditiert von der Zentralstelle der Länder für Sicherheitstechnik (ZLS) und der Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten (ZLG).

Notifiziert unter der Nr. 0197 bei der Kommission der Europäischen Gemeinschaft.

CE Das CE Kennzeichen darf bei Einhaltung aller zutreffenden EG-Richtlinien angebracht werden. CE

Fig. 49 Approval of the quality management system of GeTeMed

I. General Information

Introduction

In this chapter you will find information on the intended purpose of VitaGuard® and some general information on its usage.

Intended use of VG 300

Alarm generation when pulse rate or SpO_2 are outside of the allowed limits.

VitaGuard® VG 300 is intended to be used for continuous, non-invasive monitoring of oxygen saturation and pulse rate of adult, paediatric and neonate patients in hospitals, hospital-type facilities, intra-hospital transport and the home. An alarm is generated if the pulse rate or the oxygen saturation falls below or exceeds preset limits. The delay times before alarms are generated can be individually programmed.

VitaGuard® VG 300 is a warning device that generates an alarm. YOU, the caregiver, must act in the event of an emergency.

Responsibility

The manufacturer takes no responsibility for any damages resulting from using the monitor in any way other than the intended use. Remember that VitaGuard® is a warning device and that YOU must act in the event of an emergency.

Allergies.

The LNOP® Neo and NeoPt sensors are especially designed for neonates to allow monitoring over a period of months without causing irritation of the skin. In seldom cases allergic reactions can occur. Should this happen, consult your clinician for advise.

Compliance with the legal requirements

The product VitaGuard® complies with all legal requirements listed in the appendix I (basic requirements on medical products) of the EEC directive on medical products. When applied according to the intended use and observing all the stated warnings there are no safety risks known to be caused by the product.

The monitor must be returned for inspection to the manufacturer, if the operation period printed on the monitor is expired.

TÜV

DOC 1/1; Rev. 0

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Anlage zu
Registrier Nr.: **HD 9911907 01**
Bericht Nr.: **C 9912944 E 02**

Hersteller:
GeTeMed Gesellschaft für
Technische Medizin mbH
Oderstraße 59
D 14513 Teltow

Geltungsbereich:

- CardioLink CL 100 / CL 1000	(11-411)
- CardioDay 200, 300, 500, 1000, 300D, 500D, 1000D	(11-411)
- Babyguard BS 1000	(12-662)
- VitaGuard VG 300, VG 2000, VG 3000	(12-662)
- Werner & Müller GmbH RW 300, RW 2000, RW 3000	(12-662)
- Messer Medical GmbH PX 1, SD 1, SD 2	(12-662)

Köln, den 07.12.1999

Dipl.-Ing. Munkler

TÜV Rheinland Product Safety GmbH – TÜV Rheinland – Zertifizierungsstelle

Fig. 50 Covered products of GeTeMeds quality management system

VII. Glossary

Alarm Parameters
Limits for monitored data, that, if exceeded, generate alarms.

Asystolie, Asystolea
Complete (at least temporary) stop of the heart beat.

BPM
Beats per minute of the heart.

Bradycardia
Slow heart rate.

(Event) delay
This is the minimal duration an event must last to generate an alarm.

LCD
Liquid Crystal Display: A special kind of a passive, non-luminous display. VitaGuard® employs an LCD to conserve battery power for a longer monitoring period.

LNOP®
Low Noise Optical Probe; a patented (Masimo Corporation) sensor type to receive noise-reduced optical signals for SpO_2 determination.

low Perfusion
here: Special SET®-analysis method employed with patients with low perfusion.

Oxygen Saturation
Ratio of oxygenated haemoglobin to all haemoglobin in arterial blood. Abbr.: SpO_2 – partial saturation of oxygen.

In this manual this term is always used for partial (functional) arterial oxygen saturation, which is the ratio between oxygenated to all **functional** haemoglobin. The normal value for adults is about 98%.

Plethysmograph
Plethysmographs primarily measure variations in limb volume or circumference that are caused by blood flow to and from that limb. VitaGuard® utilises the optical bridge of the LNOP®-sensor to detect the changes in opacity resulting from the periodic filling and emptying of the blood vessels.

Plethysmogram
Display of the results of a plethysmograph, showing the time-course of the blood flow in the observed vessel

Table of Content

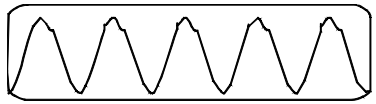

Fig. 51 Example of a plethysmogram as displayed on the VitaGuard® VG 300

SET®
Signal Extraction Technology: A patented (Masimo Corporation) procedure to determine the arterial SpO_2 value in noisy environments e.g. due to motion and low perfusion.

Silent Alarms
Special internal alarm limits that cause episodes to be stored without actually generating an acoustic alarm. For example, a silent lower bradycardia limit of 100 BPM may be set. If the pulse rate falls below 100 BPM, then a silent alarm will be stored. If the real alarm limit is set to 80 BPM and the pulse rate falls below this value, then a real alarm with warn tone is generated.

SpO_2
See oxygen saturation.

Tachycardia
Rapid heart rate.

Technical Alarm
A technical alarm is a slow sequence of warning tones that are generated when a technical irregularity is detected, for example, when the SpO_2 sensor is not properly connected.

Trend
In this manual: Displaying average values to show and review a longer period of data.

VIII. Index

EMERGENCY SITUATION

Please ask the handling physician how you should act in the event of an emergency. For baby monitoring purposes we offer an alarm chart with instructions on how to act in an emergency. Read those instructions carefully. If you do not fully understand them, ask your paediatrician or your dealer. Make certain you and all other potential caregivers are ready to respond properly to an alarm. Every caregiver must be able to perform CPR (cardiopulmonary resuscitation) alone or be able to instruct a second person to assist in CPR. **We recommend to participate in a CPR training course.** Recapitulate the necessary actions with all potential caregivers regularly, at least once every month!

In the event of an alarm, follow the instructions on page ii.

IMPORTANT – Telephone numbers in an emergency!

Please note the telephone numbers of your doctors in the spaces provided below:

Emergency: _____

Family doctor: _____

Your address:

Name: _____

Street: _____

Postal code: _____

Telephone: _____

Keep this manual in a place where it can easily be found by every potential caregiver!

Operator Manual

VitaGuard®

(Serial number 0199701 or greater)

VG 300
Pulse oximeter
incorporating Masimo SET® Technology

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HighTech made easy

GeTeMed GmbH

Operator manual VG 300
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